

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **ABRILADA**®

**adalimumab injection**

**40 mg/0.8 mL**

#### **Prefilled Pen for Subcutaneous Injection**

Read this carefully before you start taking **Abrilada** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Abrilada**.

**Abrilada** is a biosimilar biologic drug (biosimilar) to the reference biologic drug Humira®. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

Before starting, during and after treatment with **Abrilada**, you/your child should be checked for active or inactive tuberculosis infection with a tuberculin skin test.

Any medicine can have side effects. Like all medicines that affect your/your child's immune system, **Abrilada** can cause serious side effects. The possible serious side effects include:

### Serious Warnings and Precautions

- **Allergic reactions:** If you/your child develop a severe rash, swollen face or difficulty breathing while taking Abrilada, call your/your child's doctor right away.
- **Hepatosplenic T-cell lymphoma:** Very rare reports of hepatosplenic T-cell lymphoma (HSTCL), a rare serious lymphoma that is often fatal, have been identified in patients treated with adalimumab. Most patients had also been treated with other medications for Crohn's disease and the majority were in adolescent and young adult males. The link between HSTCL and adalimumab is not clear.
- **Other cancers:** There have been very rare cases of certain kinds of cancer in patients taking adalimumab or other TNF-blockers. Some patients receiving adalimumab have developed types of cancer called non-melanoma skin cancer. Tell your/your child's doctor if you/your child have a bump or open sore that does not heal. People with more serious rheumatoid arthritis that have had the disease for a long time may have a higher than average risk of getting a kind of cancer that affects the lymph system, called lymphoma. If you/your child take Abrilada, or other TNF-blockers, your/your child's risk may increase. There have been cases of lymphoma and other cancers, including unusual types, in children, adolescents and young adults taking TNF-blocking agents, including adalimumab, which sometimes resulted in death. For children and adults taking TNF-blocker medicines, the chances of developing lymphoma or other cancers may increase.
- **Lupus-like symptoms:** Some patients have developed lupus-like symptoms that got better after their treatment was stopped. If you/your child have chest pains that do not go away, shortness of breath, joint pain or a rash on your/your child's cheeks or arms that gets worse in the sun, call your/your child's doctor right away. Your/your child's doctor may decide to stop your/your child's treatment.
- **Nervous system diseases:** There have been rare cases of disorders that affect the nervous system of people taking adalimumab or other TNF-blockers. Signs that you/your child could be experiencing a problem affecting your/your child's nervous system include: numbness or tingling, problems with your/your child's vision, weakness in your/your child's legs, and dizziness.
- **Serious infections:** There have been rare cases where patients taking adalimumab or other TNF-blocking agents have developed serious infections. Some of these cases have been life-threatening. Such infections include tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis). Infection causes include tuberculosis, legionellosis (a serious form of bacterial pneumonia), listeriosis (an infection that usually develops after eating food contaminated by bacteria called listeria), and very rare cases of hepatitis B infection relapse.
- **Blood problems:** In some instances, patients treated with TNF-blocking agents may develop low blood counts, such as anemia (low red blood cells) or low platelets. If you/your child develop symptoms such as persistent fever, bleeding, or bruising, you should contact your/your child's doctor right away.

### **What is Abrilada used for?**

Abrilada treatment should be started and supervised by specialist physicians experienced in the diagnosis and treatment of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), adult and pediatric Crohn's disease (CD), adult and pediatric ulcerative colitis (UC), adult and adolescent hidradenitis suppurativa (HS), psoriasis (Ps) or adult and pediatric uveitis, and familiar with the Abrilada efficacy and safety profile.

Abrilada is a medicine that is used in:

- adults with rheumatoid arthritis, which is an inflammatory disease of the joints.
- adults with psoriatic arthritis, which is an inflammatory disease of the joints and skin.
- adults with ankylosing spondylitis, which is a form of arthritis.
- adults with Crohn's disease, which is an inflammatory disease of the digestive tract.
- patients 2 years of age and older who have polyarticular juvenile idiopathic arthritis.
- children 13 to 17 years weighing  $\geq 40$  kg who have severe Crohn's disease or who have Crohn's disease which has not responded to other usual treatments.
- adults with ulcerative colitis, which is an inflammatory disease of the bowel (colon).
- adults or adolescents (12 to 17 years of age, weighing  $\geq 30$  kg) with moderate to severe hidradenitis suppurativa (HS) who have not responded to antibiotics. HS is a painful, progressive, chronic inflammatory skin disease that causes nodules, abscesses, sinus tracts and fistulas under the breasts, underarms, buttocks and groin.
- adults with psoriasis, which is an inflammatory disease of the skin. The doctor prescribed Abrilada to reduce the signs and symptoms of your plaque psoriasis.
- adults with uveitis, which is an inflammatory disease of the eye.
- children with chronic non-infectious uveitis from 2 years of age with inflammation affecting the front of the eye.
- children 5 to 17 years of age who have ulcerative colitis.

Patients with rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, hidradenitis suppurativa, psoriasis, or uveitis may be given other medicines for their disease before they are given Abrilada. If you have ulcerative colitis or you/your child have Crohn's disease, you/your child will first be given other medicines. If you/your child do not respond well enough to these medicines, you/your child will be given Abrilada to reduce the signs and symptoms of your/your child's disease.

### **How does Abrilada work?**

Abrilada is a fully human monoclonal antibody produced by cultured cells. Monoclonal antibodies are proteins that recognize and bind to other unique proteins. Abrilada binds to a specific protein called TNF-alpha (also known as tumor necrosis factor). People with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, adult and pediatric ulcerative colitis, hidradenitis suppurativa or psoriasis have too much of TNF-alpha in their bodies. The extra TNF-alpha in your/your child's body can attack normal healthy body tissues and cause inflammation, especially in the tissues of your/your child's bones, cartilage, joints, digestive tract and skin. By binding to TNF-alpha, Abrilada decreases the inflammation process of these diseases.

Abrilada helps reduce the signs and symptoms of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis and psoriatic arthritis (such as pain and swollen joints), may help improve your/your child's ability to perform daily activities (such as getting dressed, walking and climbing stairs), and may help prevent further damage to your/your child's bones and joints. In addition, Abrilada helps reduce the signs and symptoms of ankylosing spondylitis (back pain and morning stiffness), and adult and pediatric Crohn's disease or ulcerative colitis (abdominal pain and diarrhea). Abrilada may also help normalize childhood growth and pubertal development, and improve the quality of life in children who have Crohn's disease (such as body image, functional and social skills, and emotional health). Abrilada may help improve the work productivity and activity impairment in caregivers of children with Crohn's disease.

Abrilada is also used to treat inflammatory lesions (nodules and abscesses) in adults and adolescents (12 to 17 years of age, weighing  $\geq$  30 kg) with hidradenitis suppurativa.

Abrilada also helps reduce the signs and symptoms of psoriasis (such as pain, itching and scaly patches on skin).

Abrilada helps control uveitis by reducing the risk of inflammation and loss of vision in adult and pediatric patients.

Abrilada, however, can also lower your/your child's body's ability to fight infections. Taking Abrilada can make you/your child more prone to getting infections or make any infection you/your child have worse.

### **What are the ingredients in Abrilada?**

Medicinal ingredients: adalimumab

Non-medicinal ingredients: edetate disodium dihydrate, L-histidine, L-histidine hydrochloride monohydrate, L-methionine, polysorbate 80, sucrose and water for injection

### **Abrilada comes in the following dosage forms:**

Prefilled Pen: Single dose, 1 mL auto-injector containing 40 mg adalimumab dissolved in 0.8 mL sterile solution (50 mg/mL).

The syringe plunger stopper and needle cover are not made with natural rubber latex.

### **Do not use Abrilada if you/your child have:**

- an allergy to any of the ingredients in Abrilada (see **What are the ingredients in Abrilada?** section).
- a serious infection such as tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis).
- moderate to severe heart failure (NYHA class III/IV).

**To help avoid side effects and ensure proper use, talk to your/your child's healthcare professional before you/your child take Abrilada. Talk about any health conditions or problems you/your child may have, including if:**

- you/your child have or have had any kind of infection including an infection that is in only one place in your/your child's body (such as an open cut or sore), or an infection that is in your/your child's whole body (such as the flu). Having an infection could put you/your child at risk for serious side effects from Abrilada. If you are unsure, ask your/your child's doctor.
- you/your child have a history of infections that keep coming back or other conditions that might increase your/your child's risk of infections, including fungal infections.
- you/your child have ever had tuberculosis, or if you/your child have been in close contact with someone who has had tuberculosis. If you/your child develop any of the symptoms of tuberculosis (a dry cough that doesn't go away, weight loss, fever, night sweats) call your/your child's doctor right away. Your/your child's doctor will need to examine you/your child for tuberculosis and perform a skin test.
- you/your child resided or travelled to areas where there is a greater risk for certain kinds of infections such as tuberculosis, histoplasmosis, coccidioidomycosis, blastomycosis, or parasitic infections. These infections are caused by a bacteria or a fungus that can affect the lungs or other parts of your/your child's body. If you/your child take Abrilada these may become active or more severe. If you don't know if you/your child have lived in or travelled to an area where these infections are common, ask your/your child's doctor.
- you/your child have ever had liver injury or hepatitis B virus infection or are at risk of developing this infection. Signs and symptoms include the following: yellowing of the skin or eyes (jaundice), feeling of sickness, tiredness, loss of appetite, joint pain, fever, dark brown-colored urine, vomiting, and abdominal pain. If you/your child experience any of these signs and symptoms, contact your/your child's doctor immediately. These symptoms may occur several months after starting therapy with Abrilada.
- you/your child experience any numbness or tingling or have ever had a disease that affects your/your child's nervous system like multiple sclerosis or Guillain-Barré syndrome.
- you/your child have or have had heart failure.
- you/your child are scheduled to have major surgery or dental procedures.
- you/your child are scheduled to be vaccinated for anything. It is recommended that pediatric patients, if possible, be brought up to date with all immunizations according to current guidelines before starting Abrilada.
- you/your child are taking other medicines for your/your child's rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, psoriasis, or other conditions. You/your child can take other medicines provided your/your child's doctor has prescribed them or has told you it is acceptable that you/your child take them while you/your child are taking Abrilada. It is important that you tell your/your child's doctor about any other medicines you/your child are taking for other conditions (for example, high blood pressure medicine) before you/your child start taking Abrilada.
- you/your child are taking other medicines for your/your child's Crohn's disease or other conditions. You/your child can take other medicines provided your/your child's doctor has prescribed them or has told you it is acceptable that you/your child take them while you/your child are taking Abrilada. It is important that you tell the doctor about any other medicines you/your child are taking for other conditions before you/your child start taking Abrilada.

- you/your child are taking any over-the-counter drugs, herbal medicines and vitamin and mineral supplements.
- you/your child are pregnant or could become pregnant.
- you/your child are breast-feeding or plan to breast-feed.

***If you/your child are not sure or have any questions about any of this information, ask your/your child's doctor.***

**Other warnings you should know about:**

If you/your child received Abrilada while pregnant, your/her baby may be at higher risk for getting an infection for up to approximately five months after the last dose of Abrilada received during pregnancy. It is important that you tell your/her baby's doctors and other healthcare professionals about your/her Abrilada use during pregnancy so they can decide when your/her baby should receive any vaccine.

**Tell your/your child's healthcare professional about all the medicines you/your child take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with Abrilada:**

You/your child should not take Abrilada with:

- other TNF-blockers such as Enbrel<sup>®</sup>, Remicade<sup>®</sup>, Cimzia<sup>®</sup>, or Simponi<sup>®</sup>
- abatacept (Orencia<sup>®</sup>)
- anakinra (Kineret<sup>®</sup>)

If you have questions, ask your/your child's doctor.

**How to take Abrilada:**

Abrilada is administered by injection under the skin (by subcutaneous injection).

**Usual dose:**

**Adults with Rheumatoid Arthritis, Psoriatic Arthritis or Ankylosing Spondylitis:**

- The recommended dose is 40 mg administered every other week as a subcutaneous injection.

**Patients, aged 2 years and older, with polyarticular juvenile idiopathic arthritis:**

- weighing 10 kg to less than 30 kg: the recommended dose of Abrilada is 20 mg every other week.
- weighing 30 kg or more: the recommended dose of Abrilada is 40 mg every other week.

For patients who do not require a full 40 mg dose of Abrilada, a 40 mg vial, a 10 mg prefilled syringe or a 20 mg prefilled syringe is also available.

**Adults with Crohn's Disease or Ulcerative Colitis:**

- The recommended induction dose is 160 mg at Week 0 (dose can be administered as four injections in one day or as two injections per day for two consecutive days), followed by 80 mg at Week 2.
- The recommended maintenance dose regimen is 40 mg every other week beginning at Week 4.

**Adults with Hidradenitis Suppurativa:**

- The recommended initial dose is 160 mg, followed by 80 mg two weeks later. The first dose of 160 mg can be administered as four injections in one day or as two injections per day for two consecutive days. The second dose of 80 mg is given as two 40 mg injections in one day.
- The recommended maintenance dose regimen is 40 mg every week beginning four weeks after the initial dose.

**Adults with Psoriasis or Uveitis:**

- The recommended dose is an initial dose of 80 mg, followed by 40 mg given every other week starting one week after the initial dose.

**Children, 13 to 17 years of age weighing  $\geq$  40 kg, with Crohn's disease:**

- The recommended dose is 160 mg initially at Week 0 (given as four 40 mg injections in one day, or as two 40 mg injections per day for two consecutive days), followed by 80 mg at Week 2 (given as two 40 mg injections). At Week 4, you/your child will begin a maintenance dose of 20 mg every other week. Depending on your/your child's response, the doctor may increase the dose to 40 mg every other week (given as one 40 mg injection).

For children who do not require a full 40 mg dose of Abrilada, a 40 mg vial or a 20 mg pre-filled syringe is also available.

**Adolescents, 12 to 17 years of age weighing  $\geq$  30 kg, with Hidradenitis Suppurativa:**

- The recommended initial dose is 80 mg administered by subcutaneous injection, followed by 40 mg every other week starting one week later. Depending on your/your child's response, the doctor may increase the dose to 40 mg every week.

**Children, from 2 years of age with Uveitis:**

- weighing less than 30 kg: the usual dose of Abrilada is 20 mg every other week with methotrexate. Your child's doctor may also prescribe an initial dose of 40 mg to be administered one week prior to the start of the usual dose if your child is older than 6 years of age.
- weighing 30 kg or more: the usual dose of Abrilada is 40 mg every other week with methotrexate. Your child's doctor may also prescribe an initial dose of 80 mg to be administered one week prior to the start of the usual dose.

For children who do not require a full 40 mg dose of Abrilada, a 40 mg vial is also available.

**Children, from 5 to 17 years of age with Ulcerative Colitis:**

- weighing less than 40 kg: the induction dose of Abrilada is 80 mg at Week 0, followed by 40 mg at Week 2. The recommended Abrilada maintenance dose regimen is 40 mg every other week or 20 mg every week beginning at Week 4.
- weighing 40 kg or more: the induction dose of Abrilada is 160 mg at Week 0, followed by 80 mg at Week 2. The recommended Abrilada maintenance dose regimen is 80 mg every other week or 40 mg every week beginning at Week 4.

**Overdose:**

If you/your child accidentally inject Abrilada more frequently than instructed, contact your/your child's doctor or local poison control centre right away.

If you think you, or a person you are caring for, have taken too much Abrilada, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you/your child forget to give yourself/your child an injection, you/your child should inject the missed dose of Abrilada as soon as you/your child remember. Then administer the next dose as you would have on the originally scheduled date.

**What are possible side effects from using Abrilada?**

These are not all the possible side effects you may have when taking Abrilada. If you experience any side effects not listed here, tell your healthcare professional.

Like all medicines, Abrilada can cause side effects. Most side effects are mild to moderate. However, some may be serious and require treatment.

Tell your/your child's doctor immediately if you/your child experience any of the following:

- severe rash, hives or other signs of allergic reaction
- swollen face, hands, feet
- trouble breathing, swallowing
- sudden weight gain; this is possibly indicative of new or worsening heart failure
- bruising or bleeding very easily, looking very pale; this could mean a blood problem such as low red blood cells (anemia) or low platelets.

Tell the doctor as soon as possible if you/your child notice any of the following:

- signs of infection such as fever, malaise, wounds, dental problems, burning on urination
- feeling weak or tired
- coughing
- tingling
- numbness
- double vision
- arm or leg weakness
- arm or leg pain, swelling or redness
- bump or open sore that does not heal
- red scaly patches or raised bumps that are filled with pus; this could be new or worsening hidradenitis suppurativa, new or worsening psoriasis or a skin infection
- alopecia (loss of hair)
- changes in the colour of the skin
- changes in the colour of your/your child's urine (dark or red)
- worsening of the appearance of a scar
- night sweats
- weight loss



- pain in the abdomen or chest

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>VERY COMMON</b>			
Injection site reaction		✓	
<b>COMMON</b>			
Cough and cold symptoms, including sorethroat		✓	
Headache	✓		
Rash		✓	
Nausea		✓	
Pneumonia		✓	✓
Fever		✓	
Abdominal pain	✓		
<b>UNCOMMON</b>			
Tuberculosis		✓	✓
Other serious infections		✓	✓
Nerve disorder		✓	✓
Appendicitis		✓	✓
Blood clots: abdominal pain, chest pain, leg or arm pain with redness and swelling		✓	✓
Bladder infection (painful urination)		✓	✓
Hepatitis (jaundice [yellow skin, dark urine], abdominal pain, tiredness)		✓	✓

If you/your child have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### General Advice About Prescription Medicines

Talk to your/your child's doctor or other healthcare provider if you/your child have any questions about this medicine or your/your child's condition. Medicines are sometimes prescribed for purposes other than those listed in a **PATIENT MEDICATION INFORMATION** leaflet. If you/your child have any concerns about this medicine, ask the doctor. The doctor or pharmacist can give you/your child information about this medicine that was written for healthcare professionals. Do not use this medicine for a

condition for which it was not prescribed. Do not share this medicine with other people. A toll-free information service is also available at 1-800-463-6001.

### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

- Store Abrilada prefilled pen in the refrigerator between 2°C to 8°C.
- Store Abrilada prefilled pen in the original carton until use to protect it from direct sunlight.
- **Do not freeze Abrilada prefilled pen.** Do not use Abrilada prefilled pen if frozen, even if it has been thawed.
- Refrigerated Abrilada may be used until the expiration date printed on the Abrilada carton or prefilled pen. Do not use Abrilada after the expiration date.
- If needed, for example when you are traveling, you may also store Abrilada at room temperature up to 30°C for a single period of up to 30 days. Store Abrilada in the original carton until use to protect it from direct sunlight.
- Throw away Abrilada if it has been kept at room temperature and not been used within the 30-day period.
- Record the date you first remove Abrilada from the refrigerator in the spaces provided on the Abrilada prefilled pen carton.
- Do not store Abrilada in extreme heat or cold.
- The medicine in Abrilada should be clear and colorless to very light brown. Do not use a prefilled pen if the liquid is cloudy, discolored, or has flakes or particles in it.
- Care should be taken to avoid dropping or crushing the product as it contains a glass syringe.
- Single use. Discard unused portion.

**Keep Abrilada, injection supplies, and all other medicines out of the reach and sight of children.**

### If you want more information about Abrilada:

- Talk to your/your child's healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](http://hc-sc.gc.ca/index-eng.php) (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website <http://www.pfizer.ca>, or by calling Pfizer Canada ULC at 1-800-463-6001

This leaflet was prepared by Pfizer Canada ULC

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<sup>Pr</sup>**ABRILADA**<sup>®</sup>

**adalimumab injection**

**40 mg/0.8 mL**

**Prefilled Pen for Subcutaneous Injection**

**INSTRUCTIONS FOR USE (IFU)**

**Keep this leaflet. These instructions show step by step directions on how to prepare and give an injection.**

**Storage information:**

- Store Abrilada prefilled pen in the refrigerator between 2°C to 8°C.
- Store Abrilada prefilled pen in the original carton until use to protect it from direct sunlight.
- **Do not freeze Abrilada prefilled pen. Do not** use Abrilada prefilled pen if frozen, even if it has been thawed.
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- **Do not** store Abrilada in extreme heat or cold.
- The medicine in Abrilada should be clear and colorless to very light brown. **Do not** use a prefilled pen if the liquid is cloudy, discolored, or has flakes or particles in it.
- Care should be taken to avoid dropping or crushing the product as it contains a glass syringe.
- Single use. Discard unused portion.

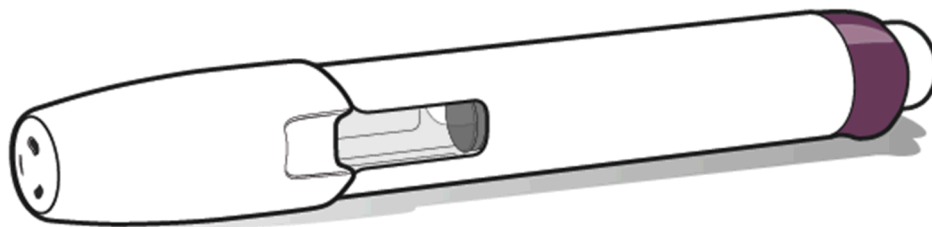
**Keep Abrilada, injection supplies, and all other medicines out of the reach and sight of children.**

Abrilada comes in a disposable (throw away) single-use prefilled pen that contains a single dose of medicine.

Abrilada can be given by a patient, caregiver or healthcare provider.

**Do not** try to inject Abrilada yourself until you have read and understood the Instructions for Use. If your/your child's healthcare provider decides that you or a caregiver may be able to give your/your child injections of Abrilada at home, you should receive training on the right way to prepare and inject Abrilada.

It is also important to talk to your/your child's healthcare provider to be sure you understand the Abrilada dosing instructions. To help you remember when to inject Abrilada, you can mark your calendar ahead of time. Call your/your child's healthcare provider if you have any questions about the right way to inject Abrilada.



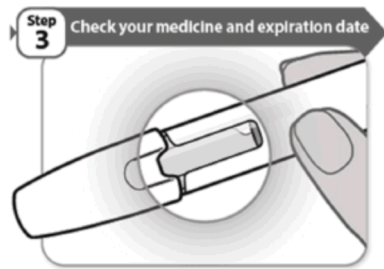
### Step 1. Supplies you need

- You will need the following supplies for each injection of Abrilada. Find a clean, flat surface to place the supplies on.
  - 1 Abrilada prefilled pen (included inside the carton)
  - 1 alcohol swab (not included in your/your child's Abrilada carton)
  - 1 cotton ball or gauze pad (not included in your/your child's Abrilada carton)
  - 1 puncture resistant sharps disposal container for pen disposal (not included in your/your child's Abrilada carton). See Step 10 "Dispose of used prefilled pen" at the end of this Instructions for Use.

### Step 2. Getting ready

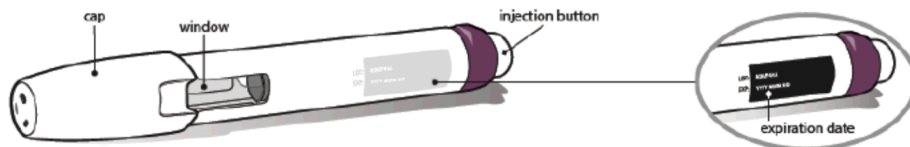
- Remove the Abrilada carton from the refrigerator.
- Make sure the name Abrilada appears on the carton and prefilled pen label.
- Take out 1 Abrilada prefilled pen. Keep the prefilled pen out of direct sunlight. Put the original carton with any unused prefilled pens back in the refrigerator.
- **Do not** use the prefilled pen if:
  - the prefilled pen or the carton containing the prefilled pen has been dropped
  - it has been frozen or thawed
  - it has been kept in direct sunlight
  - it appears to be damaged
  - the seals on a new carton are broken
  - it has been out of the refrigerator for more than 30 days
  - the expiration date has passed
  - the liquid is cloudy, discolored or has flakes or particles
- For a more comfortable injection, you may leave the prefilled pen at room temperature for 15 to 30 minutes before your injection.
- **Do not** warm Abrilada in any other way (for example, do not warm it in a microwave or in hot water).
- **Do not** shake the prefilled pen. Shaking can damage your medicine.
- Wash your hands with soap and water, and dry completely.
- **Do not** remove the cap until you are ready to inject.

### Step 3. Check your/your child's medicine and expiration date

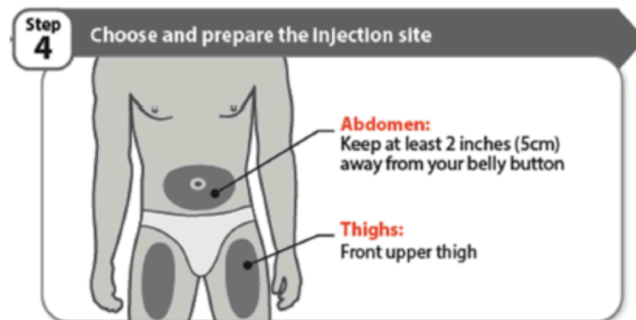


- Look carefully at the medicine in the window.
- Make sure the medicine in the prefilled pen is clear and colorless to very light brown and free from flakes or particles.
- It is normal to see one or more air bubbles in the window.
- Check the expiration date on the prefilled pen label. The location of the expiration date on the prefilled pen label is shown below. **Do not** use the pen if the expiration date has passed.

If you have any questions about your medicine, please contact your/your child's healthcare provider or pharmacist.



### Step 4. Choose and prepare the injection site



- Choose a different site each time you give an injection.
  - Only use the front of your/your child's thighs or lower abdomen (belly) as shown. If you choose the abdomen, do not use the area 5 cm around the belly button (navel).
  - Each new injection should be given at least 3 cm from a site you used before.
- **Do not** inject into bony areas or areas on the skin that are bruised, red, sore (tender) or hard. Avoid injecting into areas with scars or stretch marks.

- If you/your child have psoriasis, do not inject directly into any raised, thick, red, or scaly skin patches or lesions on the skin.
- **Do not** inject through clothes.
- Wipe the injection site with the alcohol swab.
- Allow the injection site to dry. **Do not** fan or blow on the clean area.
- **Do not** touch this area again before giving the injection.

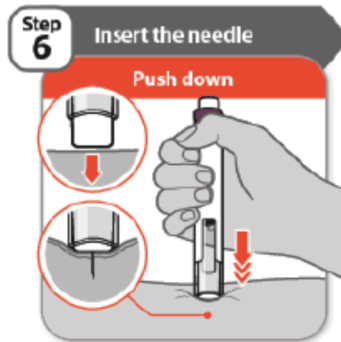
#### Step 5. Remove the cap



- Twist and pull off the cap.
  - Throw the cap away into a sharps disposal container. You will not need it again.
- Important:** Handle the prefilled pen with care to avoid an accidental needle stick injury.

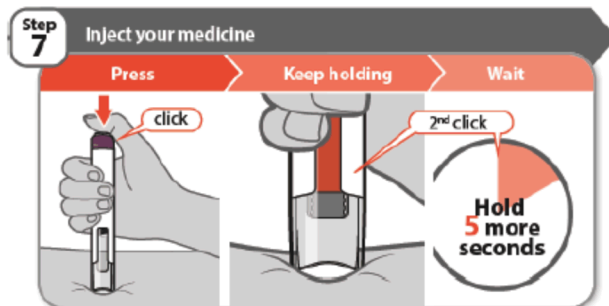
**Note:** The needle cover stays inside the cap after removal.

#### Step 6. Insert the needle



- **Push** the prefilled pen firmly against the skin at 90 degrees, as shown in the diagram.
- Note:** The needle goes into the skin as you push the prefilled pen down. You will only be able to press down the injection button in Step 7 when you are pushing down firmly enough.
- **Keep the prefilled pen pushed against the skin until Step 9.**

#### Step 7. Inject your medicine



- **Press** the injection button all the way down and you will hear a click. The click means the start of the injection.
- **Keep holding** the prefilled pen firmly against the skin while the orange bar moves across the window. You will hear a 2<sup>nd</sup> click.
- **Wait** for at least 5 more seconds after the 2<sup>nd</sup> click to make sure you/your child get the full dose of medicine.

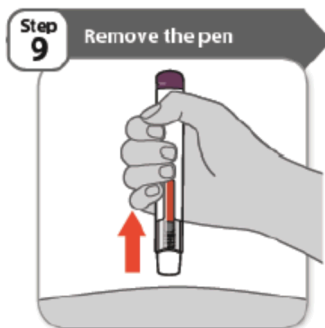
**Note:** If you cannot press down the injection button, it is because you are not pushing the prefilled pen down firmly enough. See the Question and Answer section for more information on what to do if the injection button does not press down.

#### Step 8. Check the window



- You should see an orange bar in the window.
- **Do not remove the prefilled pen until you have waited at least 5 seconds after the 2<sup>nd</sup> click and until the orange bar completely fills the window.**

#### Step 9. Remove the prefilled pen





- **Remove** the prefilled pen from the skin.  
**Note:** After you remove the prefilled pen from the skin, the needle will be automatically covered.
- If the window has not turned orange, this means you/your child have not received a full dose. Call your/your child’s healthcare provider or pharmacist right away.
- **Do not inject another dose.**

#### Step 10. Dispose of used prefilled pen



- **Do not** throw away (dispose of) prefilled pens in your household trash or recycle bin.
- Put the used prefilled pen in a puncture resistant sharp disposal container right away after use.
- If you do not have a container made especially for this purpose (sharp container), you may use a hard plastic container with a screw-on cap or metal container with a plastic lid labelled “Used Syringes”. Do not use glass or clear plastic containers.
- Always keep the container out of the sight and reach of children.
- When the container is about two-thirds full, tape the cap or lid down so it does not come off and dispose of it as instructed by your/your child’s doctor, nurse or pharmacist. **DO NOT THROW THE CONTAINER IN THE HOUSEHOLD TRASH OR RECYCLING BIN.**
- You should follow any special provincial or local laws regarding the proper disposal of needles and syringes.

#### Step 11. After your injection



- Look closely at the injection site. If there is blood, use a clean cotton ball or gauze pad to press lightly on the injection area for a few seconds.
- **Do not** rub the injection site.

**Note:** Store any unused prefilled pens in the refrigerator in the original carton.

## **Questions and Answers**

### **What should I do with the prefilled pen if it has been dropped?**

Do not use it, even if it looks undamaged. Dispose of the prefilled pen in the same way as a used prefilled pen. You will need to use a new prefilled pen to give you/your child's injection.

### **Can I use the prefilled pen straight from the refrigerator?**

Yes, however you may find that using the prefilled pen at room temperature reduces stinging or discomfort. If you allow the prefilled pen to reach room temperature before use, you must keep it away from direct sunlight as this can damage your medicine.

### **What should I do if I need to travel?**

When you are traveling, you may store the prefilled pen in its carton at room temperature up to 30°C for up to 30 days.

### **Is it okay to shake the prefilled pen before I use it?**

No, do not shake the prefilled pen. Shaking can damage the medicine. When you check the medicine, gently tilt the prefilled pen back and forth while looking carefully into the window. It is normal to see one or more air bubbles.

### **Do I need to remove any air bubbles before using the prefilled pen?**

No, do not attempt to remove air bubbles.

### **Drops of medicine have appeared at the needle tip. Is this okay?**

Yes, it is normal to see a few drops of medicine at the needle tip when you remove the cap.

### **Can I re-insert the needle if I change my mind where I want to inject?**

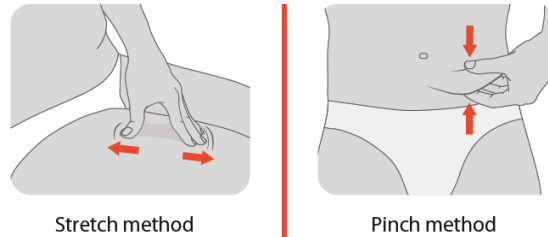
No, you **should not** re-insert the needle into your/your child's skin. If you change your mind, you will need a replacement prefilled pen if the needle has already been inserted into the skin. After the injection button has been pressed, you must not lift the prefilled pen from the skin until the injection has finished.

### **I pushed the prefilled pen against the skin but could not press the button down. What should I do?**

Take your finger off the injection button and push your prefilled pen down more firmly against the skin. Then try pushing the button again. If this does not work, stretching the skin may make the injection site firmer, making pressing the injection button easier.

### **Can I pinch or stretch the skin at the injection area?**

Yes, pinching or stretching the skin before injection may make the injection site firmer, making it easier to press the injection button.



**Do I need to keep my finger pressed on the injection button for the whole injection?**

No, you can stop pressing the button when the injection has started. However, make sure you keep holding the prefilled pen firmly against the skin. The prefilled pen will continue to deliver the medicine.

**How long will the injection take?**

From the time the dose begins until you hear the 2<sup>nd</sup> click, it usually takes 3 to 10 seconds. After the 2<sup>nd</sup> click, you should continue to hold your prefilled pen in place for at least 5 more seconds to make sure you give the full dose.

**What should I do if I see more than a small drop of medicine on the skin after giving the injection?**

Nothing this time, but for your next injection wait a little longer before removing the prefilled pen from the skin to make sure all of the medicine went into your/your child's skin.

**What should I do if I have any questions about the Abrilada prefilled pen or medicine?**

Contact your/your child's healthcare provider or pharmacist.

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **ABRILADA**<sup>®</sup>

**adalimumab injection**

**10 mg/0.2 mL, 20 mg/0.4mL, 40 mg/0.8 mL**

#### **Single dose Prefilled Syringe for Subcutaneous Injection**

Read this carefully before you start taking **Abrilada** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Abrilada**.

**Abrilada** is a biosimilar biologic drug (biosimilar) to the reference biologic drug Humira<sup>®</sup>. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

Before starting, during and after treatment with **Abrilada**, you/your child should be checked for active or inactive tuberculosis infection with a tuberculin skin test.

Any medicine can have side effects. Like all medicines that affect your/your child's immune system, **Abrilada** can cause serious side effects. The possible serious side effects include:

### Serious Warnings and Precautions

- **Allergic reactions:** If you/your child develop a severe rash, swollen face or difficulty breathing while taking Abrilada, call your/your child's doctor right away.
- **Hepatosplenic T-cell lymphoma:** Very rare reports of hepatosplenic T-cell lymphoma (HSTCL), a rare serious lymphoma that is often fatal, have been identified in patients treated with adalimumab. Most patients had also been treated with other medications for Crohn's disease and the majority were in adolescent and young adult males. The link between HSTCL and adalimumab is not clear.
- **Other cancers:** There have been very rare cases of certain kinds of cancer in patients taking adalimumab or other TNF-blockers. Some patients receiving adalimumab have developed types of cancer called non-melanoma skin cancer. Tell your/your child's doctor if you/your child have a bump or open sore that does not heal. People with more serious rheumatoid arthritis that have had the disease for a long time may have a higher than average risk of getting a kind of cancer that affects the lymph system, called lymphoma. If you/your child take Abrilada, or other TNF-blockers, your/your child's risk may increase. There have been cases of lymphoma and other cancers, including unusual types, in children, adolescents and young adults taking TNF-blocking agents, including adalimumab, which sometimes resulted in death. For children and adults taking TNF-blocker medicines, the chances of developing lymphoma or other cancers may increase.
- **Lupus-like symptoms:** Some patients have developed lupus-like symptoms that got better after their treatment was stopped. If you/your child have chest pains that do not go away, shortness of breath, joint pain or a rash on your/your child's cheeks or arms that gets worse in the sun, call your/your child's doctor right away. Your/your child's doctor may decide to stop your/your child's treatment.
- **Nervous system diseases:** There have been rare cases of disorders that affect the nervous system of people taking adalimumab or other TNF-blockers. Signs that you/your child could be experiencing a problem affecting your/your child's nervous system include: numbness or tingling, problems with your/your child's vision, weakness in your/your child's legs, and dizziness.
- **Serious infections:** There have been rare cases where patients taking adalimumab or other TNF-blocking agents have developed serious infections. Some of these cases have been life-threatening. Such infections include tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis). Infection causes include tuberculosis, legionellosis (a serious form of bacterial pneumonia), listeriosis (an infection that usually develops after eating food contaminated by bacteria called listeria), and very rare cases of hepatitis B infection relapse.
- **Blood problems:** In some instances, patients treated with TNF-blocking agents may develop low blood counts, such as anemia (low red blood cells) or low platelets. If you/your child develop symptoms such as persistent fever, bleeding, or bruising, you should contact your/your child's doctor right away.

## **What is Abrilada used for?**

Abrilada treatment should be started and supervised by specialist physicians experienced in the diagnosis and treatment of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), adult and pediatric Crohn's disease (CD), adult and pediatric ulcerative colitis (UC), adult and adolescent hidradenitis suppurativa (HS), psoriasis (Ps) or adult and pediatric uveitis, and familiar with the Abrilada efficacy and safety profile.

Abrilada is a medicine that is used in:

- adults with rheumatoid arthritis, which is an inflammatory disease of the joints.
- adults with psoriatic arthritis, which is an inflammatory disease of the joints and skin.
- adults with ankylosing spondylitis, which is a form of arthritis.
- adults with Crohn's disease, which is an inflammatory disease of the digestive tract.
- patients 2 years of age and older who have polyarticular juvenile idiopathic arthritis.
- children 13 to 17 years weighing  $\geq 40$  kg who have severe Crohn's disease or who have Crohn's disease which has not responded to other usual treatments.
- adults with ulcerative colitis, which is an inflammatory disease of the bowel (colon).
- adults or adolescents (12 to 17 years of age, weighing  $\geq 30$  kg) with moderate to severe hidradenitis suppurativa (HS) who have not responded to antibiotics. HS is a painful, progressive, chronic inflammatory skin disease that causes nodules, abscesses, sinus tracts and fistulas under the breasts, underarms, buttocks and groin.
- adults with psoriasis, which is an inflammatory disease of the skin. The doctor prescribed Abrilada to reduce the signs and symptoms of your plaque psoriasis.
- adults with uveitis, which is an inflammatory disease of the eye.
- children with chronic non-infectious uveitis from 2 years of age with inflammation affecting the front of the eye.
- children 5 to 17 years of age who have ulcerative colitis.

Patients with rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, hidradenitis suppurativa, psoriasis, or uveitis may be given other medicines for their disease before they are given Abrilada. If you have ulcerative colitis or you/your child have Crohn's disease, you/your child will first be given other medicines. If you/your child do not respond well enough to these medicines, you/your child will be given Abrilada to reduce the signs and symptoms of your/your child's disease.

## **How does Abrilada work?**

Abrilada is a fully human monoclonal antibody produced by cultured cells. Monoclonal antibodies are proteins that recognize and bind to other unique proteins. Abrilada binds to a specific protein called TNF-alpha (also known as tumor necrosis factor). People with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, adult and pediatric ulcerative colitis, hidradenitis suppurativa or psoriasis have too much of TNF-alpha in their bodies. The extra TNF-alpha in your/your child's body can attack normal healthy body tissues and cause inflammation, especially in the tissues of your/your child's bones, cartilage, joints, digestive tract and skin. By binding to TNF-alpha, Abrilada decreases the inflammation process of these diseases.

Abrilada helps reduce the signs and symptoms of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis and psoriatic arthritis (such as pain and swollen joints), may help improve your/your child's

ability to perform daily activities (such as getting dressed, walking and climbing stairs), and may help prevent further damage to your/your child's bones and joints. In addition, Abrilada helps reduce the signs and symptoms of ankylosing spondylitis (back pain and morning stiffness), and adult and pediatric Crohn's disease or ulcerative colitis (abdominal pain and diarrhea). Abrilada may also help normalize childhood growth and pubertal development, and improve the quality of life in children who have Crohn's disease (such as body image, functional and social skills, and emotional health). Abrilada may help improve the work productivity and activity impairment in caregivers of children with Crohn's disease.

Abrilada is also used to treat inflammatory lesions (nodules and abscesses) in adults and adolescents (12 to 17 years of age, weighing  $\geq$  30 kg) with hidradenitis suppurativa.

Abrilada also helps reduce the signs and symptoms of psoriasis (such as pain, itching and scaly patches on skin).

Abrilada helps control uveitis by reducing the risk of inflammation and loss of vision in adult and pediatric patients.

Abrilada, however, can also lower your/your child's body's ability to fight infections. Taking Abrilada can make you/your child more prone to getting infections or make any infection you/your child have worse.

### **What are the ingredients in Abrilada?**

Medicinal ingredients: adalimumab

Non-medicinal ingredients: edetate disodium dihydrate, L-histidine, L-histidine hydrochloride monohydrate, L-methionine, polysorbate 80, sucrose and water for injection

### **Abrilada comes in the following dosage forms:**

Prefilled Syringe:

- Single dose, 1 mL prefilled glass syringe containing 40 mg adalimumab dissolved in 0.8 mL sterile solution (50 mg/mL)
- Single dose, 1 mL prefilled glass syringe containing 20 mg adalimumab dissolved in 0.4 mL sterile solution (50 mg/mL)
- Single dose, 1 mL prefilled glass syringe containing 10 mg adalimumab dissolved in 0.2 mL sterile solution (50 mg/mL)

The syringe plunger stopper and needle cover are not made with natural rubber latex.

### **Do not use Abrilada if you/your child have:**

- an allergy to any of the ingredients in Abrilada (see **What are the ingredients in Abrilada?** section).
- a serious infection such as tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis).
- moderate to severe heart failure (NYHA class III/IV).

**To help avoid side effects and ensure proper use, talk to your/your child's healthcare professional before you/your child take Abrilada. Talk about any health conditions or problems you/your child may have, including if:**

- you/your child have or have had any kind of infection including an infection that is in only one place in your/your child's body (such as an open cut or sore), or an infection that is in your/your child's whole body (such as the flu). Having an infection could put you/your child at risk for serious side effects from Abrilada. If you are unsure, ask your/your child's doctor.
- you/your child have a history of infections that keep coming back or other conditions that might increase your/your child's risk of infections, including fungal infections.
- you/your child have ever had tuberculosis, or if you/your child have been in close contact with someone who has had tuberculosis. If you/your child develop any of the symptoms of tuberculosis (a dry cough that doesn't go away, weight loss, fever, night sweats) call your/your child's doctor right away. Your/your child's doctor will need to examine you/your child for tuberculosis and perform a skin test.
- you/your child resided or travelled to areas where there is a greater risk for certain kinds of infections such as tuberculosis, histoplasmosis, coccidioidomycosis, blastomycosis, or parasitic infections. These infections are caused by a bacteria or a fungus that can affect the lungs or other parts of your/your child's body. If you/your child take Abrilada these may become active or more severe. If you don't know if you/your child have lived in or travelled to an area where these infections are common, ask your/your child's doctor.
- you/your child have ever had liver injury or hepatitis B virus infection or are at risk of developing this infection. Signs and symptoms include the following: yellowing of the skin or eyes (jaundice), feeling of sickness, tiredness, loss of appetite, joint pain, fever, dark brown-colored urine, vomiting, and abdominal pain. If you/your child experience any of these signs and symptoms, contact your/your child's doctor immediately. These symptoms may occur several months after starting therapy with Abrilada.
- you/your child experience any numbness or tingling or have ever had a disease that affects your/your child's nervous system like multiple sclerosis or Guillain-Barré syndrome.
- you/your child have or have had heart failure.
- you/your child are scheduled to have major surgery or dental procedures.
- you/your child are scheduled to be vaccinated for anything. It is recommended that pediatric patients, if possible, be brought up to date with all immunizations according to current guidelines before starting Abrilada.
- you/your child are taking other medicines for your/your child's rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, psoriasis, or other conditions. You/your child can take other medicines provided your/your child's doctor has prescribed them or has told you it is acceptable that you/your child take them while you/your child are taking Abrilada. It is important that you tell your/your child's doctor about any other medicines you/your child are taking for other conditions (for example, high blood pressure medicine) before you/your child start taking Abrilada.
- you/your child are taking other medicines for your/your child's Crohn's disease or other conditions. You/your child can take other medicines provided your/your child's doctor has prescribed them or has told you it is acceptable that you/your child take them while you/your child are taking Abrilada.



It is important that you tell the doctor about any other medicines you/your child are taking for other conditions before you/your child start taking Abrilada.

- you/your child are taking any over-the-counter drugs, herbal medicines and vitamin and mineral supplements.
- you/your child are pregnant or could become pregnant.
- you/your child are breast-feeding or plan to breast-feed.

***If you/your child are not sure or have any questions about any of this information, ask your/your child's doctor.***

**Other warnings you should know about:**

If you/your child received Abrilada while pregnant, your/her baby may be at higher risk for getting an infection for up to approximately five months after the last dose of Abrilada received during pregnancy. It is important that you tell your/her baby's doctors and other healthcare professionals about your/her Abrilada use during pregnancy so they can decide when your/her baby should receive any vaccine.

**Tell your/your child's healthcare professional about all the medicines you/your child take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with Abrilada:**

You/your child should not take Abrilada with:

- other TNF-blockers such as Enbrel<sup>®</sup>, Remicade<sup>®</sup>, Cimzia<sup>®</sup>, or Simponi<sup>®</sup>
- abatacept (Orencia<sup>®</sup>)
- anakinra (Kineret<sup>®</sup>)

If you have questions, ask your/your child's doctor.

**How to take Abrilada:**

Abrilada is administered by injection under the skin (by subcutaneous injection).

**Usual dose:**

**Adults with Rheumatoid Arthritis, Psoriatic Arthritis or Ankylosing Spondylitis:**

- The recommended dose is 40 mg administered every other week as a subcutaneous injection.

**Patients, aged 2 years and older, with polyarticular juvenile idiopathic arthritis:**

- weighing 10 kg to less than 30 kg: the recommended dose of Abrilada is 20 mg every other week.
- weighing 30 kg or more: the recommended dose of Abrilada is 40 mg every other week.

For patients who do not require a full 40 mg dose of Abrilada, a 40 mg vial, a 10 mg prefilled syringe or a 20 mg prefilled syringe is also available.

**Adults with Crohn's Disease or Ulcerative Colitis:**

- The recommended induction dose is 160 mg at Week 0 (dose can be administered as four injections in one day or as two injections per day for two consecutive days), followed by 80 mg at Week 2.
- The recommended maintenance dose regimen is 40 mg every other week beginning at Week 4.

**Adults with Hidradenitis Suppurativa:**

- The recommended initial dose is 160 mg, followed by 80 mg two weeks later. The first dose of 160 mg can be administered as four injections in one day or as two injections per day for two consecutive days. The second dose of 80 mg is given as two 40 mg injections in one day.
- The recommended maintenance dose regimen is 40 mg every week beginning four weeks after the initial dose.

**Adults with Psoriasis or Uveitis:**

- The recommended dose is an initial dose of 80 mg, followed by 40 mg given every other week starting one week after the initial dose.

**Children, 13 to 17 years of age weighing  $\geq$  40 kg, with Crohn's disease:**

- The recommended dose is 160 mg initially at Week 0 (given as four 40 mg injections in one day, or as two 40 mg injections per day for two consecutive days), followed by 80 mg at Week 2 (given as two 40 mg injections). At Week 4, you/your child will begin a maintenance dose of 20 mg every other week. Depending on your/your child's response, the doctor may increase the dose to 40 mg every other week (given as one 40 mg injection).

For children who do not require a full 40 mg dose of Abrilada, a 40 mg vial or a 20 mg pre-filled syringe is also available.

**Adolescents, 12 to 17 years of age weighing  $\geq$  30 kg, with Hidradenitis Suppurativa:**

- The recommended initial dose is 80 mg administered by subcutaneous injection, followed by 40 mg every other week starting one week later. Depending on your/your child's response, the doctor may increase the dose to 40 mg every week.

**Children, from 2 years of age with Uveitis:**

- weighing less than 30 kg: the usual dose of Abrilada is 20 mg every other week with methotrexate. Your child's doctor may also prescribe an initial dose of 40 mg to be administered one week prior to the start of the usual dose if your child is older than 6 years of age.
- weighing 30 kg or more: the usual dose of Abrilada is 40 mg every other week with methotrexate. Your child's doctor may also prescribe an initial dose of 80 mg to be administered one week prior to the start of the usual dose.

For children who do not require a full 40 mg dose of Abrilada, a 40 mg vial is also available.

**Children, from 5 to 17 years of age with Ulcerative Colitis:**

- weighing less than 40 kg: the induction dose of Abrilada is 80 mg at Week 0, followed by 40 mg at Week 2. The recommended Abrilada maintenance dose regimen is 40 mg every other week or 20 mg every week beginning at Week 4.
- weighing 40 kg or more: the induction dose of Abrilada is 160 mg at Week 0, followed by 80 mg at Week 2. The recommended Abrilada maintenance dose regimen is 80 mg every other week or 40 mg every week beginning at Week 4.

**Overdose:**

If you/your child accidentally inject Abrilada more frequently than instructed, contact your/your child's doctor or local poison control centre right away.

If you think you, or a person you are caring for, have taken too much Abrilada, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you/your child forget to give yourself/your child an injection, you/your child should inject the missed dose of Abrilada as soon as you/your child remember. Then administer the next dose as you would have on the originally scheduled date.

**What are possible side effects from using Abrilada?**

These are not all the possible side effects you may have when taking Abrilada. If you experience any side effects not listed here, tell your healthcare professional.

Like all medicines, Abrilada can cause side effects. Most side effects are mild to moderate. However, some may be serious and require treatment.

Tell your/your child's doctor immediately if you/your child experience any of the following:

- severe rash, hives or other signs of allergic reaction
- swollen face, hands, feet
- trouble breathing, swallowing
- sudden weight gain; this is possibly indicative of new or worsening heart failure
- bruising or bleeding very easily, looking very pale; this could mean a blood problem such as low red blood cells (anemia) or low platelets.

Tell the doctor as soon as possible if you/your child notice any of the following:

- signs of infection such as fever, malaise, wounds, dental problems, burning on urination
- feeling weak or tired
- coughing
- tingling
- numbness
- double vision
- arm or leg weakness
- arm or leg pain, swelling or redness
- bump or open sore that does not heal
- red scaly patches or raised bumps that are filled with pus; this could be new or worsening hidradenitis suppurativa, new or worsening psoriasis or a skin infection
- alopecia (loss of hair)
- changes in the colour of the skin
- changes in the colour of your/your child's urine (dark or red)
- worsening of the appearance of a scar
- night sweats

- weight loss
- pain in the abdomen or chest

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>VERY COMMON</b>			
Injection site reaction		√	
<b>COMMON</b>			
Cough and cold symptoms, including sorethroat		√	
Headache	√		
Rash		√	
Nausea		√	
Pneumonia		√	√
Fever		√	
Abdominal pain	√		
<b>UNCOMMON</b>			
Tuberculosis		√	√
Other serious infections		√	√
Nerve disorder		√	√
Appendicitis		√	√
Blood clots: abdominal pain, chest pain, leg or arm pain with redness and swelling		√	√
Bladder infection (painful urination)		√	√
Hepatitis (jaundice [yellow skin, dark urine], abdominal pain, tiredness)		√	√

If you/your child have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

#### General Advice About Prescription Medicines

Talk to your/your child's doctor or other healthcare provider if you/your child have any questions about this medicine or your/your child's condition. Medicines are sometimes prescribed for purposes other

than those listed in a **PATIENT MEDICATION INFORMATION** leaflet. If you/your child have any concerns about this medicine, ask the doctor. The doctor or pharmacist can give you/your child information about this medicine that was written for healthcare professionals. Do not use this medicine for a condition for which it was not prescribed. Do not share this medicine with other people. A toll-free information service is also available at 1-800-463-6001.

### **Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

- Store Abrilada prefilled syringe in the refrigerator between 2°C to 8°C.
- Store Abrilada prefilled syringe in the original carton until use to protect it from direct sunlight.
- **Do not freeze Abrilada prefilled syringe.** Do not use Abrilada prefilled syringe if frozen, even if it has been thawed.
- Refrigerated Abrilada may be used until the expiration date printed on the Abrilada carton or prefilled syringe. Do not use Abrilada after the expiration date.
- If needed, for example when you are traveling, you may also store Abrilada at room temperature up to 30°C for a single period of up to 30 days. Store Abrilada in the original carton until use to protect it from direct sunlight.
- Throw away Abrilada if it has been kept at room temperature and not been used within the 30-day period.
- Record the date you first remove Abrilada from the refrigerator in the spaces provided on the Abrilada prefilled syringe carton.
- Do not store Abrilada in extreme heat or cold.
- The medicine in Abrilada should be clear and colorless to very light brown. Do not use a prefilled syringe if the liquid is cloudy, discolored, or has flakes or particles in it.
- Do not drop or crush Abrilada. The prefilled syringe is glass.
- Single use. Discard unused portion.

**Keep Abrilada, injection supplies, and all other medicines out of the reach and sight of children.**

### **If you want more information about Abrilada:**

- Talk to your/your child's healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](http://hc-) (<http://hc->

sc.gc.ca/index-eng.php); the manufacturer's website <http://www.pfizer.ca>, or by calling Pfizer Canada ULC at 1-800-463-6001

This leaflet was prepared by Pfizer Canada ULC

Last Revised NOV 14, 2022

**PrABRILADA®**

**adalimumab injection 10 mg/0.2 mL, 20 mg/0.4 mL, 40 mg/0.8 mL**

**Single dose Prefilled Syringe for Subcutaneous Injection**

**INSTRUCTIONS FOR USE (IFU)**

**Keep this leaflet. These instructions show step by step directions on how to prepare and give an injection.**

**Storage Information:**

- Store Abrilada prefilled syringe in the refrigerator between 2°C to 8°C.
- Store Abrilada prefilled syringe in the original carton until use to protect it from direct sunlight.
- **Do not freeze Abrilada prefilled syringe. Do not** use Abrilada prefilled syringe if frozen, even if it has been thawed.
- Refrigerated Abrilada may be used until the expiration date printed on the Abrilada carton or prefilled syringe. **Do not** use Abrilada after the expiration date.
- If needed, for example when you are traveling, you may also store Abrilada at room temperature up to 30°C for a single period of up to 30 days. Store Abrilada in the original carton until use to protect it from direct sunlight.
- Throw away Abrilada if it has been kept at room temperature and not been used within the 30-day period.
- Record the date you first remove Abrilada from the refrigerator in the spaces provided on the Abrilada prefilled syringe carton.
- **Do not** store Abrilada in extreme heat or cold.
- The medicine in Abrilada should be clear and colorless to very light brown. **Do not** use a prefilled syringe if the liquid is cloudy, discolored, or has flakes or particles in it.
- **Do not** drop or crush Abrilada. The prefilled syringe is glass.
- Single use. Discard unused portion.

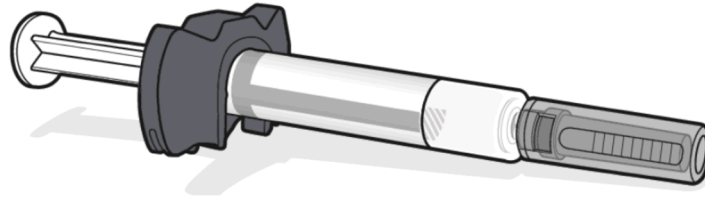
**Keep Abrilada, injection supplies, and all other medicines out of the reach and sight of children.**

Abrilada comes in a disposable (throw away) single-use prefilled syringe that contains a single dose of medicine.

Abrilada can be given by a patient, caregiver or healthcare provider.

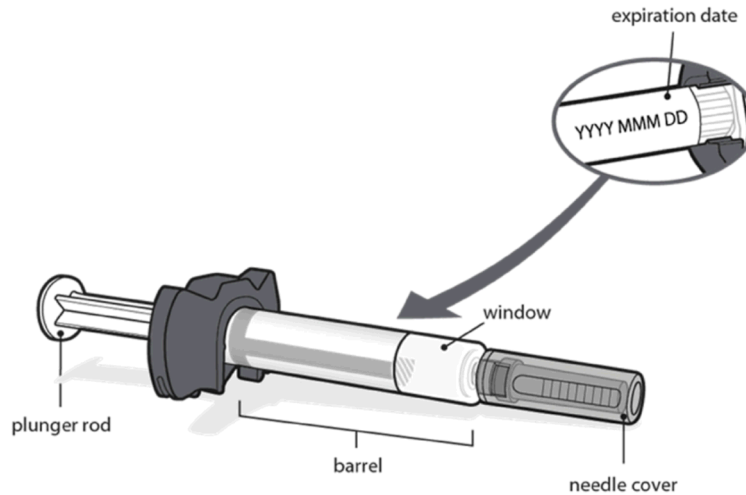
**Do not** try to inject Abrilada yourself until you have read and understood the Instructions for Use. If your/your child's healthcare provider decides that you or a caregiver may be able to give your/your child injections of Abrilada at home, you should receive training on the right way to prepare and inject Abrilada.

It is also important to talk to your/your child's healthcare provider to be sure you understand the Abrilada dosing instructions. To help you remember when to inject Abrilada, you can mark your calendar ahead of time. Call your/your child's healthcare provider if you or the caregiver have any questions about the right way to inject Abrilada. It is important that you read, understand, and follow these instructions so that you inject Abrilada the right way.



### Step 1. Supplies you need

- You will need the following supplies for each injection of Abrilada. Find a clean, flat surface to place the supplies on.
  - 1 Abrilada prefilled syringe in a tray inside the carton
  - 1 alcohol swab (not included in your/your child's Abrilada carton)
  - 1 cotton ball or gauze pad (not included in your/your child's Abrilada carton)
  - 1 puncture resistant sharps disposal container for prefilled syringe disposal (not included in your/your child's Abrilada carton). See Step 10 "Dispose of used syringe" at the end of this Instructions for Use.



### Step 2. Getting ready

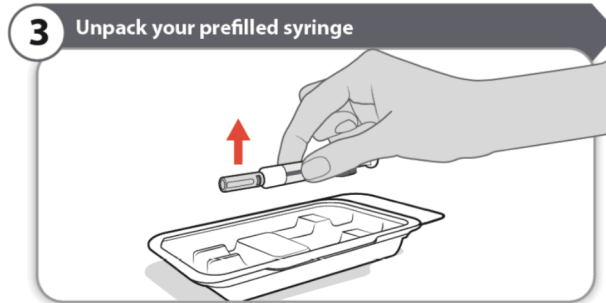
- Remove the Abrilada carton from the refrigerator.
- Open the carton and take out the tray containing your prefilled syringe.
- Make sure the name Abrilada appears on the dose tray and prefilled syringe label.
- Check the carton and tray. **Do not** use if:
  - it has been dropped
  - it has been frozen or thawed
  - it appears to be damaged
  - the seals on a new carton are broken
  - it has been out of the refrigerator for more than 30 days
  - the expiration date has passed

Wash your hands with soap and water, and dry completely.



If you have any questions about your/your child's medicine, please contact your/your child's healthcare provider or pharmacist.

### Step 3. Unpack your prefilled syringe



- Peel back the paper seal on the tray.
- Remove 1 prefilled syringe from the tray and put the original carton with any unused prefilled syringes back in the refrigerator.
- **Do not** use the syringe if:
  - o it appears to be damaged
  - o It has been kept in direct sunlight
  - o liquid is cloudy, discolored, or has flakes or particles
- Do not shake the syringe. Shaking can damage your medicine.
- For a more comfortable injection, leave the prefilled syringe at room temperature for 15 to 30 minutes before the injection.
- Do not warm Abrilada in any other way (for example, do not warm it in a microwave or in hot water).
- **Do not** remove the needle cover from the prefilled syringe until you are ready to inject.

**Always hold the prefilled syringe by the barrel to prevent damage.**

### Step 4. Check your medicine and expiration date

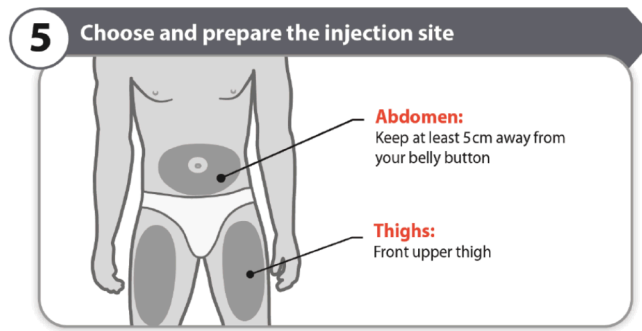


- Look carefully at the medicine in the window.
- Make sure the medicine in the prefilled syringe is clear and colorless to very light brown and free from flakes or particles.
- It is normal to see one or more air bubbles in the window.

- Check the expiration date on the prefilled syringe label as shown in the figure in Step 1. Do not use the prefilled syringe if the expiration date has passed.

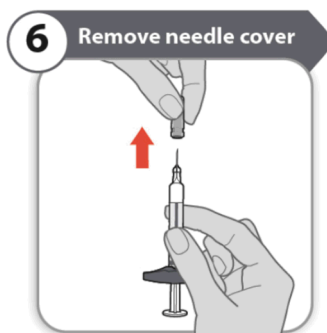
If you have any questions about the medicine, please contact your/your child's healthcare provider or pharmacist.

### Step 5. Choose and prepare the injection site



- Choose a different site each time you give an injection.
  - Only use the front of your/your child's thighs or lower abdomen (belly) as shown. If you choose the abdomen, do not use the area 5 cm around the belly button (navel).
  - Each new injection should be given at least 3 cm from a site you used before.
- **Do not** inject into bony areas or areas on the skin that are bruised, red, sore (tender) or hard. Avoid injecting into areas with scars or stretch marks.
  - If you/your child's have psoriasis, do not inject directly into any raised, thick, red, or scaly skin patches or lesions on the skin.
- **Do not** inject through clothes.
- Wipe the injection site with the alcohol swab.
- Allow the injection site to dry. **Do not** fan or blow on the clean area.
- **Do not** touch this area again before giving the injection.

### Step 6. Remove the needle cover

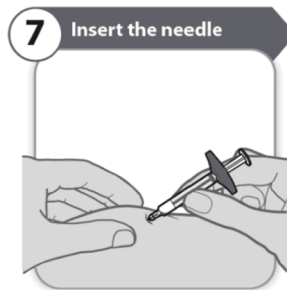


- Hold the prefilled syringe by the barrel. Carefully pull the needle cover straight off and away from your body when you are ready to inject.
- It is normal to see a drop of liquid at the end of the needle.

- Throw the needle cover away into a sharps disposal container.

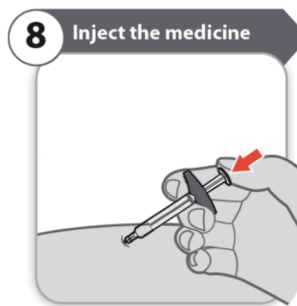
**Note:** Be careful when you handle the prefilled syringe to avoid an accidental needle stick injury.

#### Step 7. Insert the needle



- Gently pinch up a fold of skin in the cleaned injection site area.
- Insert the needle to its full depth into the skin, at a 45 degree angle, as shown.
- After the needle is inserted, release the pinched skin.

#### Step 8. Inject the medicine



- Using slow and constant pressure, push the plunger rod all the way down until the barrel is empty.

**Note:** It is recommended to hold your prefilled syringe in the skin for an additional 5 seconds after the plunger has been pressed down completely to make sure you get the full dose of medicine.

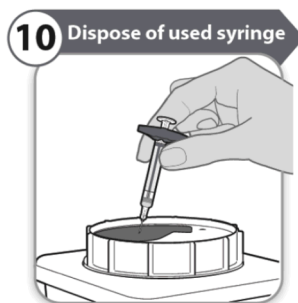
- Pull the needle out of the skin at the same angle at which it entered.

### Step 9. Check your syringe



- Check that the medicine has completely emptied from your prefilled syringe. If the gray stopper is not in the position shown, you may not have injected all of the medicine. Contact your/your child's healthcare provider right away.
- **Never re-insert the needle.**
- **Never put the cap back on the needle.**

### Step 10. Dispose of used syringe



- **Do not** throw away (dispose of) syringes in the household trash or recycling bin.
- Put the used syringe in a puncture resistant sharp disposal container right away after use.
- If you do not have a container made especially for this purpose (sharp container), you may use a hard plastic container with a screw-on cap or metal container with a plastic lid labelled "Used Syringes". Do not use glass or clear plastic containers.
- Always keep the container out of the sight and reach of children.
- When the container is about two-thirds full, tape the cap or lid down so it does not come off and dispose of it as instructed by your/your child's doctor, nurse or pharmacist. **DO NOT THROW THE CONTAINER IN THE HOUSEHOLD TRASH OR RECYCLING BIN.**
- You should follow any special provincial or local laws regarding the proper disposal of needles and syringes.

## Step 11. After your injection



- Look closely at the injection site. If there is blood, use a clean cotton ball or gauze pad to press lightly on the injection area for a few seconds.
- **Do not** rub the injection site.

**Note:** Store any unused syringes in the refrigerator in the original carton.

### Questions and Answers

#### **What should I do with the prefilled syringe if it has been dropped?**

Do not use it if it has been dropped or the carton containing the prefilled syringe has been dropped even if it looks undamaged. Dispose of the prefilled syringe in the same way as a used prefilled syringe. You will need to use a new prefilled syringe to give your/your child's injection.

#### **Can I use the prefilled syringe straight from the refrigerator?**

Yes, however you may find that using the prefilled syringe at room temperature reduces stinging or discomfort. If you allow the prefilled syringe to reach room temperature before use, you must keep it away from direct sunlight as this can damage your medicine.

#### **What should I do if I need to travel?**

When you are traveling, you may store the prefilled syringe in its carton at room temperature up to 30°C for up to 30 days.

#### **Is it okay to shake the prefilled syringe before I use it?**

No, do not shake the prefilled syringe. Shaking can damage the medicine. When you check the medicine, gently tilt the syringe back and forth while looking carefully into the window. It is normal to see one or more air bubbles.

#### **Do I need to remove any air bubbles before using the prefilled syringe?**

No, do not attempt to remove air bubbles.

#### **Drops of medicine have appeared at the needle tip. Is this okay?**

Yes, it is normal to see a few drops of medicine at the needle tip when you remove the needle cover.

#### **Can I re-insert the needle into my/my child's skin?**

No, you should not re-insert the needle into your/your child's skin. You will need a replacement prefilled syringe if the needle has already been inserted into the skin.

#### **How long will the injection take?**

Dose delivery will take approximately 2 to 5 seconds. Remember to hold the prefilled syringe in place for at least 5 seconds after the plunger has been pushed down all the way.

**What should I do if I have any questions about the prefilled syringe or medicine?**

Contact your/your child's healthcare provider or pharmacist.

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **ABRILADA**®

**adalimumab injection**

**40 mg/0.8 mL**

#### **Single dose Vial for Subcutaneous Injection**

Read this carefully before you start taking **Abrilada** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Abrilada**.

**Abrilada** is a biosimilar biologic drug (biosimilar) to the reference biologic drug Humira®. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

Before starting, during and after treatment with **Abrilada**, you/your child should be checked for active or inactive tuberculosis infection with a tuberculin skin test.

Any medicine can have side effects. Like all medicines that affect your/your child's immune system, **Abrilada** can cause serious side effects. The possible serious side effects include:

### Serious Warnings and Precautions

- **Allergic reactions:** If you/your child develop a severe rash, swollen face or difficulty breathing while taking Abrilada, call your/your child's doctor right away.
- **Hepatosplenic T-cell lymphoma:** Very rare reports of hepatosplenic T-cell lymphoma (HSTCL), a rare serious lymphoma that is often fatal, have been identified in patients treated with adalimumab. Most patients had also been treated with other medications for Crohn's disease and the majority were in adolescent and young adult males. The link between HSTCL and adalimumab is not clear.
- **Other cancers:** There have been very rare cases of certain kinds of cancer in patients taking adalimumab or other TNF-blockers. Some patients receiving adalimumab have developed types of cancer called non-melanoma skin cancer. Tell your/your child's doctor if you/your child have a bump or open sore that does not heal. People with more serious rheumatoid arthritis that have had the disease for a long time may have a higher than average risk of getting a kind of cancer that affects the lymph system, called lymphoma. If you/your child take Abrilada, or other TNF-blockers, your/your child's risk may increase. There have been cases of lymphoma and other cancers, including unusual types, in children, adolescents and young adults taking TNF-blocking agents, including adalimumab, which sometimes resulted in death. For children and adults taking TNF-blocker medicines, the chances of developing lymphoma or other cancers may increase.
- **Lupus-like symptoms:** Some patients have developed lupus-like symptoms that got better after their treatment was stopped. If you/your child have chest pains that do not go away, shortness of breath, joint pain or a rash on your/your child's cheeks or arms that gets worse in the sun, call your/your child's doctor right away. Your/your child's doctor may decide to stop your/your child's treatment.
- **Nervous system diseases:** There have been rare cases of disorders that affect the nervous system of people taking adalimumab or other TNF-blockers. Signs that you/your child could be experiencing a problem affecting your/your child's nervous system include: numbness or tingling, problems with your/your child's vision, weakness in your/your child's legs, and dizziness.
- **Serious infections:** There have been rare cases where patients taking adalimumab or other TNF-blocking agents have developed serious infections. Some of these cases have been life-threatening. Such infections include tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis). Infection causes include tuberculosis, legionellosis (a serious form of bacterial pneumonia), listeriosis (an infection that usually develops after eating food contaminated by bacteria called listeria), and very rare cases of hepatitis B infection relapse.
- **Blood problems:** In some instances, patients treated with TNF-blocking agents may develop low blood counts, such as anemia (low red blood cells) or low platelets. If you/your child develop symptoms such as persistent fever, bleeding, or bruising, you should contact your/your child's doctor right away.



## **What is Abrilada used for?**

Abrilada treatment should be started and supervised by specialist physicians experienced in the diagnosis and treatment of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), adult and pediatric Crohn's disease (CD), adult and pediatric ulcerative colitis (UC), adult and adolescent hidradenitis suppurativa (HS), psoriasis (Ps) or adult and pediatric uveitis, and familiar with the Abrilada efficacy and safety profile.

Abrilada is a medicine that is used in:

- adults with rheumatoid arthritis, which is an inflammatory disease of the joints.
- adults with psoriatic arthritis, which is an inflammatory disease of the joints and skin.
- adults with ankylosing spondylitis, which is a form of arthritis.
- adults with Crohn's disease, which is an inflammatory disease of the digestive tract.
- patients 2 years of age and older who have polyarticular juvenile idiopathic arthritis.
- children 13 to 17 years weighing  $\geq 40$  kg who have severe Crohn's disease or who have Crohn's disease which has not responded to other usual treatments.
- adults with ulcerative colitis, which is an inflammatory disease of the bowel (colon).
- adults or adolescents (12 to 17 years of age, weighing  $\geq 30$  kg) with moderate to severe hidradenitis suppurativa (HS) who have not responded to antibiotics. HS is a painful, progressive, chronic inflammatory skin disease that causes nodules, abscesses, sinus tracts and fistulas under the breasts, underarms, buttocks and groin.
- adults with psoriasis, which is an inflammatory disease of the skin. The doctor prescribed Abrilada to reduce the signs and symptoms of your plaque psoriasis.
- adults with uveitis, which is an inflammatory disease of the eye.
- children with chronic non-infectious uveitis from 2 years of age with inflammation affecting the front of the eye.
- children 5 to 17 years of age who have ulcerative colitis.

Patients with rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, hidradenitis suppurativa, psoriasis, or uveitis may be given other medicines for their disease before they are given Abrilada. If you have ulcerative colitis or you/your child have Crohn's disease, you/your child will first be given other medicines. If you/your child do not respond well enough to these medicines, you/your child will be given Abrilada to reduce the signs and symptoms of your/your child's disease.

## **How does Abrilada work?**

Abrilada is a fully human monoclonal antibody produced by cultured cells. Monoclonal antibodies are proteins that recognize and bind to other unique proteins. Abrilada binds to a specific protein called TNF-alpha (also known as tumor necrosis factor). People with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, adult and pediatric ulcerative colitis, hidradenitis suppurativa or psoriasis have too much of TNF-alpha in their bodies. The extra TNF-alpha in your/your child's body can attack normal healthy body tissues and cause inflammation, especially in the tissues of your/your child's bones, cartilage, joints, digestive tract and skin. By binding to TNF-alpha, Abrilada decreases the inflammation process of these diseases.

Abrilada helps reduce the signs and symptoms of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis and psoriatic arthritis (such as pain and swollen joints), may help improve your/your child's

ability to perform daily activities (such as getting dressed, walking and climbing stairs), and may help prevent further damage to your/your child's bones and joints. In addition, Abrilada helps reduce the signs and symptoms of ankylosing spondylitis (back pain and morning stiffness), and adult and pediatric Crohn's disease or ulcerative colitis (abdominal pain and diarrhea). Abrilada may also help normalize childhood growth and pubertal development, and improve the quality of life in children who have Crohn's disease (such as body image, functional and social skills, and emotional health). Abrilada may help improve the work productivity and activity impairment in caregivers of children with Crohn's disease.

Abrilada is also used to treat inflammatory lesions (nodules and abscesses) in adults and adolescents (12 to 17 years of age, weighing  $\geq$  30 kg) with hidradenitis suppurativa.

Abrilada also helps reduce the signs and symptoms of psoriasis (such as pain, itching and scaly patches on skin).

Abrilada helps control uveitis by reducing the risk of inflammation and loss of vision in adult and pediatric patients.

Abrilada, however, can also lower your/your child's body's ability to fight infections. Taking Abrilada can make you/your child more prone to getting infections or make any infection you/your child have worse.

### **What are the ingredients in Abrilada?**

Medicinal ingredients: adalimumab

Non-medicinal ingredients: edetate disodium dihydrate, L-histidine, L-histidine hydrochloride monohydrate, L-methionine, polysorbate 80, sucrose and water for injection

### **Abrilada comes in the following dosage forms:**

Vial: Single dose 2 mL glass vial containing 40 mg adalimumab dissolved in 0.8 mL sterile solution (50 mg/mL) for pediatric use

The vial stopper is not made with natural rubber latex.

### **Do not use Abrilada if you/your child have:**

- an allergy to any of the ingredients in Abrilada (see **What are the ingredients in Abrilada?** section).
- a serious infection such as tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis).
- moderate to severe heart failure (NYHA class III/IV).

**To help avoid side effects and ensure proper use, talk to your/your child's healthcare professional before you/your child take Abrilada. Talk about any health conditions or problems you/your child may have, including if:**

- you/your child have or have had any kind of infection including an infection that is in only one place in your/your child's body (such as an open cut or sore), or an infection that is in your/your child's whole body (such as the flu). Having an infection could put you/your child at risk for serious side effects from Abrilada. If you are unsure, ask your/your child's doctor.
- you/your child have a history of infections that keep coming back or other conditions that might increase your/your child's risk of infections, including fungal infections.
- you/your child have ever had tuberculosis, or if you/your child have been in close contact with someone who has had tuberculosis. If you/your child develop any of the symptoms of tuberculosis (a dry cough that doesn't go away, weight loss, fever, night sweats) call your/your child's doctor right away. Your/your child's doctor will need to examine you/your child for tuberculosis and perform a skin test.
- you/your child resided or travelled to areas where there is a greater risk for certain kinds of infections such as tuberculosis, histoplasmosis, coccidioidomycosis, blastomycosis, or parasitic infections. These infections are caused by a bacteria or a fungus that can affect the lungs or other parts of your/your child's body. If you/your child take Abrilada these may become active or more severe. If you don't know if you/your child have lived in or travelled to an area where these infections are common, ask your/your child's doctor.
- you/your child have ever had liver injury or hepatitis B virus infection or are at risk of developing this infection. Signs and symptoms include the following: yellowing of the skin or eyes (jaundice), feeling of sickness, tiredness, loss of appetite, joint pain, fever, dark brown-colored urine, vomiting, and abdominal pain. If you/your child experience any of these signs and symptoms, contact your/your child's doctor immediately. These symptoms may occur several months after starting therapy with Abrilada.
- you/your child experience any numbness or tingling or have ever had a disease that affects your/your child's nervous system like multiple sclerosis or Guillain-Barré syndrome.
- you/your child have or have had heart failure.
- you/your child are scheduled to have major surgery or dental procedures.
- you/your child are scheduled to be vaccinated for anything. It is recommended that pediatric patients, if possible, be brought up to date with all immunizations according to current guidelines before starting Abrilada.
- you/your child are taking other medicines for your/your child's rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, psoriasis, or other conditions. You/your child can take other medicines provided your/your child's doctor has prescribed them or has told you it is acceptable that you/your child take them while you/your child are taking Abrilada. It is important that you tell your/your child's doctor about any other medicines you/your child are taking for other conditions (for example, high blood pressure medicine) before you/your child start taking Abrilada.
- you/your child are taking other medicines for your/your child's Crohn's disease or other conditions. You/your child can take other medicines provided your/your child's doctor has prescribed them or has told you it is acceptable that you/your child take them while you/your child are taking Abrilada. It is important that you tell the doctor about any other medicines you/your child are taking for other conditions before you/your child start taking Abrilada.
- you/your child are taking any over-the-counter drugs, herbal medicines and vitamin and mineral supplements.
- you/your child are pregnant or could become pregnant.
- you/your child are breast-feeding or plan to breast-feed.

***If you/your child are not sure or have any questions about any of this information, ask your/your child's doctor.***

**Other warnings you should know about:**

If you/your child received Abrilada while pregnant, your/her baby may be at higher risk for getting an infection for up to approximately five months after the last dose of Abrilada received during pregnancy. It is important that you tell your/her baby's doctors and other healthcare professionals about your/her Abrilada use during pregnancy so they can decide when your/her baby should receive any vaccine.

**Tell your/your child's healthcare professional about all the medicines you/your child take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with Abrilada:**

You/your child should not take Abrilada with:

- other TNF-blockers such as Enbrel<sup>®</sup>, Remicade<sup>®</sup>, Cimzia<sup>®</sup>, or Simponi<sup>®</sup>
- abatacept (Orencia<sup>®</sup>)
- anakinra (Kineret<sup>®</sup>)

If you have questions, ask your/your child's doctor.

**How to take Abrilada:**

Abrilada is administered by injection under the skin (by subcutaneous injection).

**Usual dose:**

**Adults with Rheumatoid Arthritis, Psoriatic Arthritis or Ankylosing Spondylitis:**

- The recommended dose is 40 mg administered every other week as a subcutaneous injection.

**Patients, aged 2 years and older, with polyarticular juvenile idiopathic arthritis:**

- weighing 10 kg to less than 30 kg: the recommended dose of Abrilada is 20 mg every other week.
- weighing 30 kg or more: the recommended dose of Abrilada is 40 mg every other week.

For patients who do not require a full 40 mg dose of Abrilada, a 40 mg vial, a 10 mg prefilled syringe or a 20 mg prefilled syringe is also available.

**Adults with Crohn's Disease or Ulcerative Colitis:**

- The recommended induction dose is 160 mg at Week 0 (dose can be administered as four injections in one day or as two injections per day for two consecutive days), followed by 80 mg at Week 2.
- The recommended maintenance dose regimen is 40 mg every other week beginning at Week 4.

**Adults with Hidradenitis Suppurativa:**

- The recommended initial dose is 160 mg, followed by 80 mg two weeks later. The first dose of 160 mg can be administered as four injections in one day or as two injections per day for two consecutive days. The second dose of 80 mg is given as two 40 mg injections in one day.
- The recommended maintenance dose regimen is 40 mg every week beginning four weeks after the initial dose.

**Adults with Psoriasis or Uveitis:**

- The recommended dose is an initial dose of 80 mg, followed by 40 mg given every other week starting one week after the initial dose.

**Children, 13 to 17 years of age weighing  $\geq$  40 kg, with Crohn's disease:**

- The recommended dose is 160 mg initially at Week 0 (given as four 40 mg injections in one day, or as two 40 mg injections per day for two consecutive days), followed by 80 mg at Week 2 (given as two 40 mg injections). At Week 4, you/your child will begin a maintenance dose of 20 mg every other week. Depending on your/your child's response, the doctor may increase the dose to 40 mg every other week (given as one 40 mg injection).

For children who do not require a full 40 mg dose of Abrilada, a 40 mg vial or a 20 mg pre-filled syringe is also available.

**Adolescents, 12 to 17 years of age weighing  $\geq$  30 kg, with Hidradenitis Suppurativa:**

- The recommended initial dose is 80 mg administered by subcutaneous injection, followed by 40 mg every other week starting one week later. Depending on your/your child's response, the doctor may increase the dose to 40 mg every week.

**Children, from 2 years of age with Uveitis:**

- weighing less than 30 kg: the usual dose of Abrilada is 20 mg every other week with methotrexate. Your child's doctor may also prescribe an initial dose of 40 mg to be administered one week prior to the start of the usual dose if your child is older than 6 years of age.
- weighing 30 kg or more: the usual dose of Abrilada is 40 mg every other week with methotrexate. Your child's doctor may also prescribe an initial dose of 80 mg to be administered one week prior to the start of the usual dose.

For children who do not require a full 40 mg dose of Abrilada, a 40 mg vial is also available.

**Children, from 5 to 17 years of age with Ulcerative Colitis:**

- weighing less than 40 kg: the induction dose of Abrilada is 80 mg at Week 0, followed by 40 mg at Week 2. The recommended Abrilada maintenance dose regimen is 40 mg every other week or 20 mg every week beginning at Week 4.
- weighing 40 kg or more: the induction dose of Abrilada is 160 mg at Week 0, followed by 80 mg at Week 2. The recommended Abrilada maintenance dose regimen is 80 mg every other week or 40 mg every week beginning at Week 4.

**Overdose:**

If you/your child accidentally inject Abrilada more frequently than instructed, contact your/your child's doctor or local poison control centre right away.

If you think you, or a person you are caring for, have taken too much Abrilada, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you/your child forget to give yourself/your child an injection, you/your child should inject the missed dose of Abrilada as soon as you/your child remember. Then administer the next dose as you would have on the originally scheduled date.

**What are possible side effects from using Abrilada?**

These are not all the possible side effects you may have when taking Abrilada. If you experience any side effects not listed here, tell your healthcare professional.

Like all medicines, Abrilada can cause side effects. Most side effects are mild to moderate. However, some may be serious and require treatment.

Tell your/your child's doctor immediately if you/your child experience any of the following:

- severe rash, hives or other signs of allergic reaction
- swollen face, hands, feet
- trouble breathing, swallowing
- sudden weight gain; this is possibly indicative of new or worsening heart failure
- bruising or bleeding very easily, looking very pale; this could mean a blood problem such as low red blood cells (anemia) or low platelets.

Tell the doctor as soon as possible if you/your child notice any of the following:

- signs of infection such as fever, malaise, wounds, dental problems, burning on urination
- feeling weak or tired
- coughing
- tingling
- numbness
- double vision
- arm or leg weakness
- arm or leg pain, swelling or redness
- bump or open sore that does not heal
- red scaly patches or raised bumps that are filled with pus; this could be new or worsening hidradenitis suppurativa, new or worsening psoriasis or a skin infection
- alopecia (loss of hair)
- changes in the colour of the skin
- changes in the colour of your/your child's urine (dark or red)
- worsening of the appearance of a scar
- night sweats
- weight loss
- pain in the abdomen or chest

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>VERY COMMON</b>			
Injection site reaction		√	
<b>COMMON</b>			
Cough and cold symptoms, including sorethroat		√	
Headache	√		
Rash		√	
Nausea		√	
Pneumonia		√	√
Fever		√	
Abdominal pain	√		
<b>UNCOMMON</b>			
Tuberculosis		√	√
Other serious infections		√	√
Nerve disorder		√	√
Appendicitis		√	√
Blood clots: abdominal pain, chest pain, leg or arm pain with redness and swelling		√	√
Bladder infection (painful urination)		√	√
Hepatitis (jaundice [yellow skin, dark urine], abdominal pain, tiredness)		√	√

If you/your child have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### General Advice About Prescription Medicines

Talk to your/your child's doctor or other healthcare provider if you/your child have any questions about this medicine or your/your child's condition. Medicines are sometimes prescribed for purposes other than those listed in a **PATIENT MEDICATION INFORMATION** leaflet. If you/your child have any concerns about this medicine, ask the doctor. The doctor or pharmacist can give you/your child information about this medicine that was written for healthcare professionals. Do not use this medicine for a condition for which it was not prescribed. Do not share this medicine with other people. A toll-free information service is also available at 1-800-463-6001.

### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

- Store Abrilada vial in the refrigerator between 2°C to 8°C.
- Store Abrilada vial in the original carton until use to protect it from direct sunlight.
- **Do not freeze Abrilada vial.** Do not use Abrilada vial if frozen, even if it has been thawed.
- Refrigerated Abrilada may be used until the expiration date printed on the Abrilada carton or vial. Do not use Abrilada after the expiration date.
- If needed, for example when you are traveling, you may also store Abrilada at room temperature up to 30°C for a single period of up to 30 days. Store Abrilada in the original carton until use to protect it from direct sunlight.
- Throw away Abrilada if it has been kept at room temperature and not been used within the 30-day period.
- Record the date you first remove Abrilada from the refrigerator in the spaces provided on the Abrilada vial.
- Do not store Abrilada in extreme heat or cold.
- The medicine in Abrilada should be clear and colorless to very light brown. Do not use a vial if the liquid is cloudy, discolored, or has flakes or particles in it.
- Single use. Discard unused portion.

**Keep Abrilada, injection supplies, and all other medicines out of the reach and sight of children.**

### If you want more information about Abrilada:

- Talk to your/your child's healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](http://hc-sc.gc.ca/index-eng.php) (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website <http://www.pfizer.ca>, or by calling Pfizer Canada ULC at 1-800-463-6001

This leaflet was prepared by Pfizer Canada ULC

Last Revised NOV 14, 2022



Pr**ABRILADA**<sup>®</sup>

**adalimumab injection 40 mg/0.8 mL**

**Single dose Vial for Subcutaneous Injection**

### **INSTRUCTIONS FOR USE (IFU)**

The following instructions explain how to inject Abrilada. Please read the instructions carefully and follow them step-by-step. You will be instructed by your/your child's doctor or assistant on the technique of injection and the amount to give to you/your child. Do not attempt to inject until you are sure that you understand how to prepare and give the injection. After proper training, the injection can be self-administered or given by another person; for example, a healthcare professional, a family member or friend.

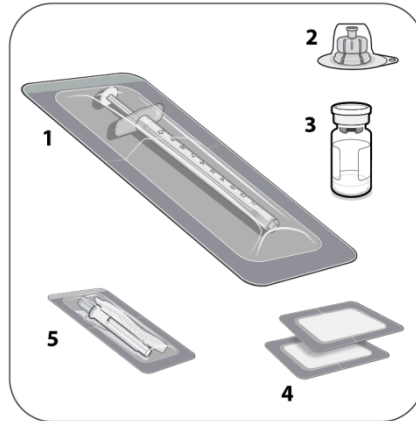
Failure to perform the following steps as described may cause contamination which may lead to an infection.

This injection should not be mixed in the same syringe or vial with any other medicine.

Abrilada comes in a single use vial that contains a single dose of medicine.

#### **Step 1. Setting up**

- Make sure you know the proper amount (volume) needed for dosing. If you don't know the amount, **STOP HERE** and contact your/your child's doctor for further instruction.
- You will need:
  - 2 alcohol swabs (not included in your/your child's Abrilada carton)
  - 1 cotton ball or gauze pad (not included in your/your child's Abrilada carton)
  - a special container for waste, such as a sharps container or as instructed by your your child's doctor or pharmacist (not included in your/your child's Abrilada carton). Place the container on your work surface. See Step 6 "Throwing away supplies" at the end of this Instructions for Use.
- Wash your hands thoroughly.
- Remove one box containing one syringe, one vial adapter, one vial and one needle from the carton. If there is a second box in the carton for a future injection, place it back in the refrigerator immediately.
- Look at the expiry date on the box to be used. **DO NOT** use any item after the date shown on the box.
- Set up the following items on a clean surface, **DO NOT** take them out of their individual packaging yet.
  - One 1 ml syringe (1)
  - One vial adapter (2)
  - One vial of Abrilada for pediatric use (3)
  - Two alcohol swabs (4)
  - One needle (5)



Abrilada is a liquid that is clear and colorless to very light brown and free from flakes or particles. **DO NOT** use if the liquid has flakes or particles in it.

### Step 2. Preparing the Abrilada dose for injection

General handling: **DO NOT** dispose of any waste items until after the injection is completed.

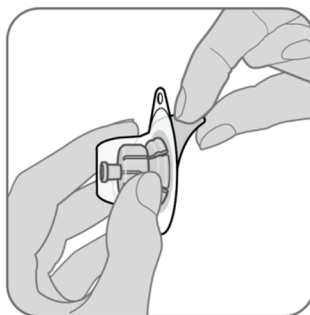
- Prepare the needle by partially peeling the package open from the end closest to the yellow syringe connector. Peel the package just far enough to expose the yellow syringe connector. Set the package down with the clear side of the package facing up.



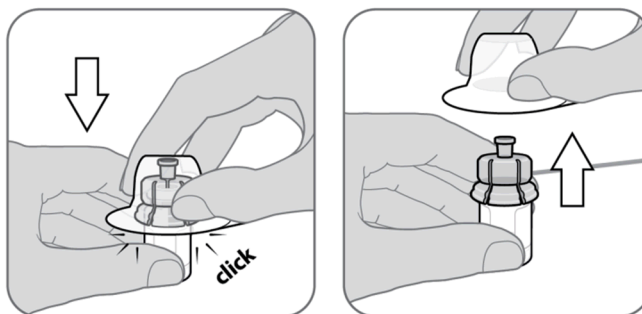
- Pop off the plastic cap from the vial to see the top of the vial stopper.



- Use one of the alcohol swabs to wipe the vial stopper. **DO NOT** touch the vial stopper after wiping with the alcohol swab.
- Peel the cover off the vial adapter package but do not take out the vial adapter.



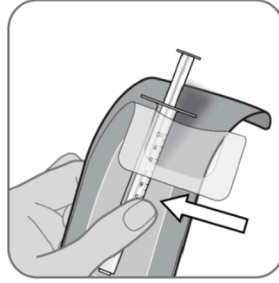
- Hold the vial with the vial stopper facing up.
- With the vial adapter still in the clear package, attach it to the vial stopper by pushing down until the vial adapter snaps in place.
- When you are sure the adapter is attached to the vial, lift off the package from the vial adapter.
- Gently set the vial with vial adapter down on your clean work surface. Be careful that it does not fall over. **DO NOT** touch the vial adapter.



- Prepare the syringe by partially peeling the package open from the end closest to the white plunger rod.
- Peel the clear package just far enough to expose the white plunger rod, but do not take the syringe out of the package.
- Hold the syringe package and **SLOWLY** pull the white plunger rod out to 0.1 mL beyond the prescribed dose (For example, if the prescribed dose is 0.5 mL, pull the white plunger rod to 0.6 mL). **NEVER** pull past the 0.9 mL position regardless of prescribed dose.
- You will set the volume to the prescribed dose in a later step.
- **DO NOT** pull the white plunger rod completely out of the syringe.

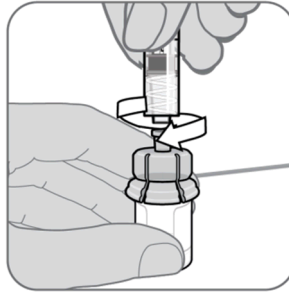
**NOTE:**

If the white plunger rod is pulled completely out of the syringe, discard the syringe and contact your/your child's Abrilada provider for a replacement. **DO NOT** try to reinsert the white plunger rod.

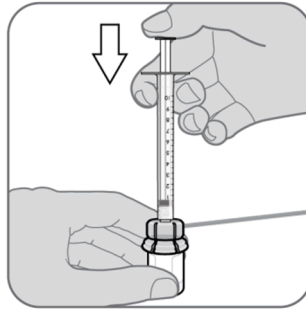


Dose + 0.1 ml

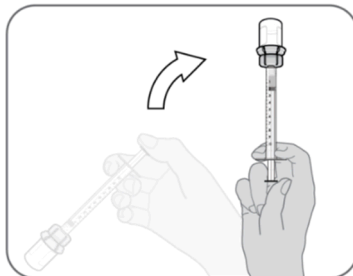
- **DO NOT** use the white plunger rod to remove the syringe from the package. Hold the syringe on the graduated area and pull the syringe from its package. **DO NOT** set the syringe down at any time.
- While holding the vial adapter firmly, insert the syringe tip into the vial adapter and twist the syringe clockwise with one hand until firm. **DO NOT** over-tighten.



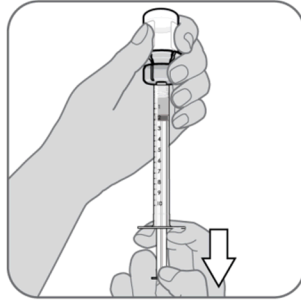
- While holding the vial, push the white plunger rod all the way down. This step is important to get the proper dose.



- Hold the white plunger rod in and turn the vial and syringe upside down.



- **SLOWLY** pull the white plunger rod out to 0.1 mL beyond the prescribed dose. This is important to get the proper dose. You will set the volume to the prescribed dose in step 4, Dose Preparation. If, for example the prescribed dose is 0.5 mL, pull the white plunger rod out to 0.6 mL. You will see the liquid medication from the vial go into the syringe.



- Push the white plunger rod all the way back in to push the liquid medication back into the vial. Again, **SLOWLY** pull the white plunger rod out to 0.1 mL beyond the prescribed dose, this is important to get the proper dose and important in order to prevent air bubbles or air gaps in the liquid medication. You will set the volume to the prescribed dose in step 4, Dose Preparation.

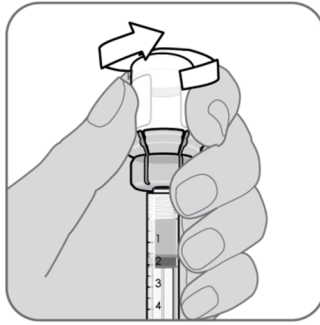


- If you see remaining air bubbles or air gaps in the liquid medication in the syringe, you may repeat this process up to 3 times. **DO NOT** shake the syringe.

**NOTE:**

If the white plunger rod is pulled completely out of the syringe, discard the syringe and contact your/your child's Abrilada provider for a replacement. **DO NOT** try to reinsert the white plunger rod.

- While still holding the syringe upright at the graduated area, remove the vial adapter with the vial by twisting the vial adapter off with the other hand. Be sure to remove the vial adapter with the vial from the syringe. **DO NOT** touch the tip of the syringe.



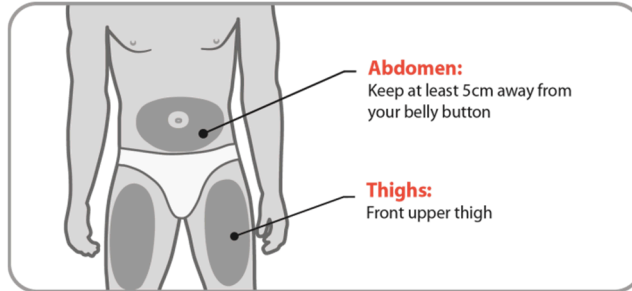
- If a large air bubble or air gap can be seen near the syringe tip, **SLOWLY** push the white plunger rod into the syringe until fluid begins to enter the syringe tip. **DO NOT** push the white plunger rod past the dose position.
- For example, if the prescribed dose is 0.5 mL, **DO NOT** push the white plunger rod past the 0.5 mL position.
- Check to see that the fluid remaining in the syringe is at least the prescribed dose volume. If the remaining volume is less than the prescribed dose volume, **DO NOT** use the syringe and contact your/your child's doctor or pharmacist.
- With your free hand, pick up the needle package with the yellow syringe connector facing down.
- Keeping the syringe up, insert the syringe tip into the yellow syringe connector and twist the syringe as indicated by the arrow in the picture until firm. The needle is now attached to the syringe.



- Pull the needle package off, but **DO NOT** remove the clear needle cap.
- Place the syringe on your clean work surface. Continue with injection site and dose preparation immediately.

### Step 3. Choosing and preparing an injection site

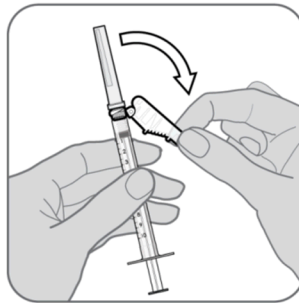
- Choose a site on the front of the thigh or the lower abdomen (belly). **DO NOT** use the same site that was used for the last injection.
- The new injection site should be given at least 3 cm from the last injection site.



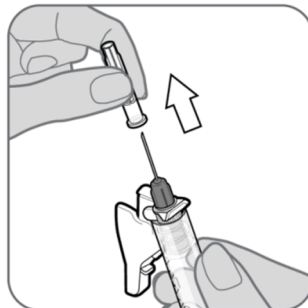
- **DO NOT** inject in an area where the skin is reddened, bruised, or hard. This may mean there is an infection and therefore you should contact your doctor.
  - If your child has psoriasis, do not inject directly into any raised, thick, red, or scaly skin patches or lesions on the skin.
- To reduce the chance of infection, wipe the injection site with the other alcohol swab. **DO NOT** touch the area again before injecting.

#### Step 4. Dose Preparation

- Pick up the syringe with the needle pointing up.
- Use your other hand to flip the pink needle cover down toward the syringe.



- Remove the clear needle cap by pulling it straight up with your other hand.

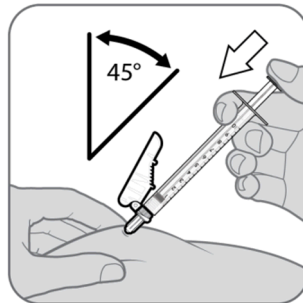


- The needle is clean.
- **DO NOT** touch the needle.
- **DO NOT** set the syringe down at any time after the clear needle cap is off.
- **DO NOT** try to put the clear needle cap back on the needle.

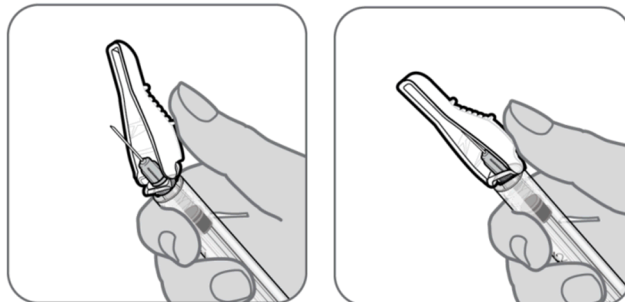
- Hold the syringe at eye-level with the needle pointing up to see the amount clearly. Be careful not to squirt the liquid medication into your eye.
- Recheck the prescribed medication amount.
- Push the white plunger rod gently into the syringe until the syringe contains the prescribed amount of liquid. Excess liquid may come out of the needle while the white plunger rod is being pushed. **DO NOT** wipe off the needle or the syringe.

#### Step 5. Injecting Abrilada

- With the free hand, gently grasp the cleaned area of skin and hold firmly.
- With the other hand, hold the syringe at a 45-degree angle to the skin.
- With one quick, short motion, push needle all the way into skin.
- Let go of the skin in your hand.
- Using slow and constant pressure, push the white plunger rod to inject the liquid medication until the syringe is empty.
- When the syringe is empty, remove the needle from the skin, being careful to pull it out at the same angle as when it was inserted.
- Check that your medicine has completely emptied from the syringe.



- Gently flip the pink needle cover up, over the needle and snap into place, and set the syringe with needle on the work surface. **DO NOT** put the clear needle cap back on the needle.



- Using a piece of gauze, apply pressure over the injection site for 10 seconds. A little bleeding may occur. **DO NOT** rub the injection site. Use a plaster if you want to.

#### Step 6. Throwing away supplies

- You will need a special container for waste, such as a puncture resistant sharp disposable container or as instructed by your/your child's doctor or pharmacist.
- Put the syringe with needle, vial and vial adapter into a special sharps container. **DO NOT** put these items into regular household waste or recycle bin.



- If you do not have a container made especially for this purpose (sharp container), you may use a hard plastic container with a screw-on cap or metal container with a plastic lid labelled "Used Syringes". Do not use glass or clear plastic containers.
- Always keep the container out of the sight and reach of children.
- When the container is about two-thirds full, tape the cap or lid down so it does not come off and dispose of it as instructed by your/your child's doctor, nurse or pharmacist. **DO NOT THROW THE CONTAINER IN THE HOUSEHOLD TRASH OR RECYCLING BIN.**
- You should follow any special provincial or local laws regarding the proper disposal of needles and syringes.
- The syringe, needle, vial and vial adapter **MUST NEVER** be reused.
- Throw away all other used items into your regular household waste.