

Important information about ABRILADA® (adalimumab)

Before you/your child use ABRILADA® (adalimumab), talk to the doctor or pharmacist if:

- you/your child have an allergy to any of the ingredients in ABRILADA® (adalimumab).
- you/your child have any medical problems, particularly those affecting the liver, kidneys or heart. This should be reviewed with your/your child's doctor before starting therapy with ABRILADA® (adalimumab).
- you/your child have or have had any kind of infection including:
 - Open cut or sore
 - Infection affecting the whole body (such as the flu)
 - History of infections that keep coming back
 - Fungal infections (such as histoplasmosis, coccidioidomycosis, blastomycosis) or resided or travelled to areas where these infections are more common
 - Parasitic infections
 - Viral infections (such as hepatitis B)
- you/your child have ever had tuberculosis been in close contact with someone who has had tuberculosis, or develop any of the symptoms of tuberculosis (a dry cough that doesn't go away, weight loss, fever, night sweats). All patients should be checked for active or inactive tuberculosis infections with a tuberculin skin test before starting therapy with ABRILADA® (adalimumab).
- 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-coloured 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® (adalimumab).
- 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® (adalimumab).
- you/your child have received in the past, or will be receiving at the same time, treatment with the immunosuppressants azathioprine or 6-mercaptopurine (6-MP). Prior or concomitant use of these medications may affect your/your child's doctor's choice to use ABRILADA® (adalimumab).

- 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® (adalimumab). 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® (adalimumab).
- 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 are not sure or have any questions about any of this information, ask your/your child's doctor.

ABRILADA® (adalimumab)

PATIENT SAFETY INFORMATION CARD

A helpful resource containing safety details to be aware of before and during treatment with ABRILADA® (adalimumab).*

* For complete safety information, please consult the Patient Medication Information leaflet contained in your product package.



ABRILADA® Registered trademark of Pfizer Inc. Used under license.
© 2024 Pfizer Canada ULC, Kirkland, Quebec H9J 2M5



PP-ABD-CAN-0054-EN



Side effects and what to do about them

Like all medicines, ABRILADA® (adalimumab) 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, how often they happen and what to do about them

Symptom/Effect	Talk with the doctor or pharmacist		Stop taking the drug and get immediate medical help
	Only if severe	In all cases	
Very common			
Injection-site reaction		X	
Common			
Coughs and cold symptoms, including sore throat		X	
Headache	X		
Rash		X	
Nausea		X	
Pneumonia		X	X
Fever		X	
Abdominal pain	X		
Uncommon			
Tuberculosis		X	X
Other serious infections		X	X
Nerve disorder		X	X
Appendicitis		X	X
Blood clots: abdominal pain, chest pain, leg or arm pain with redness and swelling		X	X
Bladder infection (painful urination)		X	X
Hepatitis (jaundice [yellow skin, dark urine], abdominal pain, tiredness)		X	X

This is not a complete list of side effects. For any unexpected effects while taking ABRILADA® (adalimumab), contact your/your child's doctor or pharmacist.

Warnings and precautions

Before starting, during and after treatment with ABRILADA® (adalimumab), 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® (adalimumab) can cause serious side effects. The possible serious side effects include:

- **Allergic reactions:** If you/your child develop a severe rash, swollen face or difficulty breathing while taking ABRILADA® (adalimumab), 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 ABRILADA® (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 who 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® (adalimumab) 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 ABRILADA® (adalimumab), which sometimes resulted in death. For children and adults taking TNF-blocker medicines, the chances of developing lymphoma or other cancers (such as breast, colon, prostate, lung and melanoma) 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 ABRILADA® (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 ABRILADA® (adalimumab) or other TNF-blocking agents have developed serious infections. Some of these cases have been life-threatening. Such infections include :

• Bacterial	• Viral (such as hepatitis B relapse)	• Pneumocystis
• Mycobacterial/tuberculosis	• Parasitic	• Pneumonia
• Invasive fungal (disseminated or extrapulmonary histoplasmosis, aspergillosis, coccidioidomycosis)	• Candidiasis	• Pyelonephritis
	• Listeriosis	• Septic arthritis
	• Legionellosis	• Septicemia
- **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.

While taking ABRILADA® (adalimumab), you/your child may receive concurrent vaccinations, except for live vaccines.

If you/your child received ABRILADA® (adalimumab) 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® (adalimumab) received during pregnancy. It is important that you tell your/her baby's doctors and other healthcare professionals about your/her ABRILADA® (adalimumab) use during pregnancy so they can decide when your/her baby should receive any vaccine.