PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrBicillin® L-A

Penicillin G benzathine injectable suspension

Read this carefully before you start taking Bicillin® L-A and each time you receive an injection. 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 Bicillin® L-A.

Serious Warnings and Precautions

- Your healthcare professional will inject Bicillin® L-A with an injection inside the muscle. Unintended injections of Bicillin® L-A into the blood vessels are associated with serious or lifethreatening side effects. Injection into or near a nerve may result in permanent nerve damage.
- Some people taking beta-lactam antibiotics including penicillin have reported severe skin reactions and serious allergic reactions, including death.
- If you have had an allergic reaction to penicillin, or other beta-lactam antibiotics, tell your healthcare professional before you start treatment with Bicillin® L-A.
- For further information and symptoms see:
 - the "To help avoid side effects and ensure proper use..." section
 - the "What are possible side effects from using..." section

What is Bicillin® L-A used for?

Bicillin® L-A is used to treat bacterial infections such as:

- strep throat [a disease that causes a sore throat (pharyngitis)]
- syphilis (a disease transmitted during sex)
- yaws, bejel and pinta (skin diseases transmitted by skin-to-skin contact)

Bicillin® L-A is also used to prevent infections that may occur after a strep throat such as:

- rheumatic fever which can cause illness in the heart, joints, skin, and brain
- glomerulonephritis (an inflammation of the kidney).

Antibacterial drugs like Bicillin® L-A treat <u>only</u> bacterial infections. They do not treat viral infections such as the common cold. Although you may feel better early in treatment, Bicillin® L-A should be used exactly as directed. Misuse or overuse of Bicillin® L-A could lead to the growth of bacteria that will not be killed by Bicillin® L-A (resistance). This means that Bicillin® L-A may not work for you in the future. Do not share your medicine.

How does Bicillin® L-A work?

Bicillin® L-A is an antibiotic that belongs to the penicillin class. It works by killing or stopping the growth of the bacteria that cause your infection.

What are the ingredients in Bicillin® L-A?

Medicinal ingredients: penicillin G benzathine

Non-medicinal ingredients: lecithin, methylparaben, povidone, propylparaben, sodium carboxymethylcellulose, sodium citrate, water for injection

Bicillin® L-A comes in the following dosage forms:

Bicillin® L-A comes as a suspension (liquid) in a 2 mL prefilled disposable syringe

Each 2 mL prefilled syringe contains 1,200,000 IU penicillin G benzathine

Do not use Bicillin® L-A if you are allergic to:

- penicillin G benzathine
- other penicillin antibiotics from the same group
- any other ingredients of Bicillin[®] L-A (see Serious Warnings and Precautions and What are the ingredients in Bicillin[®] L-A?)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Bicillin® L-A. Talk about any health conditions or problems you may have, including if you:

- are allergic to other penicillin antibiotics, cephalosporin antibiotics such as cefazolin, cephalexin etc., or any other medications. Ask your healthcare professional if you are not sure if a medication you are allergic to belongs to one of these groups of medications.
- have allergies to any food, dyes, preservative etc., hay fever, hives or asthma.
- have kidney problems.
- are pregnant or planning to become pregnant.
- are breastfeeding or planning to breastfeed. Penicillin is passed to the infant through human breast milk.

Other warnings you should know about:

Call your healthcare professional if:

- your symptoms do not improve or get worse while taking Bicillin[®] L-A
- you develop a severe skin rash or blisters with or without fever
- you experience any of the following symptoms during or over 2 months after your treatment with Bicillin® L-A: severe diarrhea (watery or bloody stools) with or without fever and stomach cramps

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

The following may interact with Bicillin® L-A:

- tetracycline (an antibiotic)
- probenecid* (to treat gout)

*Product is not marketed in Canada.

How to take Bicillin® L-A:

Your healthcare professional will inject Bicillin® L-A into a muscle of the buttocks or the hip. In infants and small children, the healthcare professional may inject Bicillin® L-A into a muscle of the thigh.

Usual dose:

The dose of Bicillin® L-A will depend on the type of infection you may have.

Your healthcare professional will calculate the right dose for you.

Your healthcare professional will also tell you how long to use Bicillin® L-A.

Ask your healthcare professional if you have any questions about how many doses of Bicillin® L-A you will need or when you will receive them.

Overdose:

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

What are possible side effects from using Bicillin® L-A?

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

If you are taking this medication to treat syphilis, you may experience side effects a few hours after the beginning of the treatment, including fever, chills, headache, muscle pain and skin reactions (Jarisch-Herxheimer reaction).

Other side effects may include:

- Itching
- Skin rash
- General tiredness
- Pain
- Headache
- Nausea, vomiting
- Swollen glands
- Pain, inflammation, infection, bleeding, bruising in the area where the medication was injected
- Sweating
- Pain in your joints and bones
- Loss of muscle mass
- Nervousness
- Unintentional shaking (tremors)
- Dizziness

- Sleepiness
- Confusion
- Memory loss
- Anxiety
- Euphoria
- Ringing in your ears
- Difference in taste
- Difficulty obtaining an erection or orgasm
- Persistent and painful erection

If they occur, they are likely to be minor and temporary. However, some may be serious and need medical attention.

Serious side effects and what to do about them				
Talk to your healtl	ncare professional	Stop taking drug and get immediate medical help		
Only if severe	In all cases			
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	Talk to your healtl Only if severe	Talk to your healthcare professional Only if severe In all cases		

Serious side effects and what to do about them				
	Talk to your healt	Stop taking drug and		
Symptom / effect	Only if severe	In all cases	get immediate medical help	
 Lung Problems: High blood pressure in your lungs Blood clots in your lungs Difficulty breathing when awake or sleeping 			٧	
Nerve and blood circulation problems in the area where the medication was injected: Loss of sensation and movement Pallor (pale skin) Blotchiness Death of skin (e.g. gangrene) (Skin symptoms may include a blue or black color, pain, numbness, and sores that produce a foul-smelling discharge) Numbness of the arm or leg Blue or black skin on the arm or leg			V	
Seizures			٧	
Hallucinations: (seeing, hearing or even feeling something that is not really there)		V		
Blood Problems: Hemolytic Anemia (a condition in which red blood cells are destroyed and removed from the bloodstream before their normal lifespan is over) Dark Urine Fatigue Pale skin color Rapid heart rate Shortness of breath Yellow skin and whites of the eyes (jaundice) Low white blood cells Fever Frequent infections that can be serious Flu-like illnesses		V		

Serious side effects and what to do about them					
Talk to your healthcare professional Stop taking					
Symptom / effect	Only if severe	In all cases	get immediate medical help		
 Low platelets (cells in the blood that help the blood clot) Abnormal bleeding Bleeding when you brush your teeth 					
Easy bruisingPinpoint red spots on the skin (petechiae)					
Abnormal Muscle Breakdown: (Rhabdomyolysis) Symptoms may include: • Dark or cola-colored urine • Muscle pain and weakness		٧			
Kidney Problems: Symptoms may include: Any change in the amount, frequency or colour of urine Fluid buildup Loss of sleep Poor appetite Upset stomach Weakness Difficulty concentrating			٧		
Vision Changes: Blurred vision		٧			
Blindness			٧		
Severe cutaneous adverse reactions (SCAR) (severe skin reactions that may also affect other organs): - skin peeling, scaling, or blistering (with or without pus) which may also affect your eyes, mouth, nose or genitals, itching, severe rash, bumps under the skin, skin pain, skin color changes (redness, yellowing, purplish)			٧		
swelling and redness of eyes or faceflu-like feeling, fever, chills, body aches, swollen glands, cough					

Serious side effects and what to do about them				
Symptom / effect	Talk to your healthcare professional		Stop taking drug and	
	Only if severe	In all cases	get immediate medical help	
- shortness of breath, chest pain or discomfort				
NOT KNOWN				
Kounis syndrome (heart problems caused by an allergic reaction): Symptoms of anaphylaxis (see above), chest pain, chest pressure or discomfort, heart palpitations, nausea or vomiting, sweating, shortness of breath, fatigue, clammy skin, feeling anxious or faint, disorientation, upset stomach.			٧	

If you 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.

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 under refrigeration (2°C to 8°C). May be removed from refrigerator and stored for 7 days at a temperature not exceeding 30°C. Protect from freezing.

Keep out of reach and sight of children.

If you want more information about Bicillin[®] L-A:

- Talk to your 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: (https://www.products/drug-products

This leaflet was prepared by Pfizer Canada ULC.

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