Bicillin® L-A

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being treated with Bicillin L-A?

Bicillin L-A contains the active ingredient benzathine benzylpenicillin. Bicillin L-A is used to treat mild-moderate infections of the upper respiratory tract and sexually transmitted infections such as syphilis, yaws, bejel and pinta. It is used to prevent the recurrence of rheumatic fever and chorea, and complications following rheumatic heart disease and severe kidney disease. For more information, see Section 1. Why am I being treated with Bicillin L-A? in the full CMI.

2. What should I know before treatment with Bicillin L-A?

You should not be given Bicillin L-A if you have ever had an allergic reaction to benzathine benzylpenicillin or any of the ingredients listed at the end of the CMI including lecithin (from soya bean) and benzoates, or if you have

experienced previous allergic reactions to any other penicillin medicine.

Talk to your doctor if you have asthma, allergies, problems with your kidneys, are sodium restricted, have had severe skin adverse reactions or diarrhoea following antibiotic use, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before treatment with Bicillin L-A? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Bicillin L-A and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How is Bicillin L-A given?

Bicillin L-A is given as an injection into deep muscle on your buttock or the front of the thigh for infants/children. More instructions can be found in Section 4. How is Bicillin L-A given? in the full CMI.

5. What should I know during treatment with Bicillin L-A?

Things you should do

- Tell your doctor straight away if: the symptoms of your infection do not improve or become worse within a few days; you have severe skin adverse reactions. diarrhoea or stomach pain, or experience anything abnormal with fingers or toes or around the injection site.
- Remind any doctor,

	dentist or pharmacist who are treating you that you are being given Bicillin L-A.	
Things you should not do	 Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist. 	
Driving or using machines	 Do not drive, operate machinery or do anything else that could be dangerous until you know how Bicillin L- 	

A affects you. It may cause dizziness or visual disturbances in some people.

For more information, see Section <u>5. What should I know</u> <u>during treatment with Bicillin L-A?</u> in the full CMI.

6. Are there any side effects?

Side effects of this medicine may include feeling anxious/nervous/abnormally happy/experience tremors; sleepiness/tiredness; nausea/vomiting; headache; excessive/abnormal sweating; muscle/joint pain; pain/ swelling along bones; worsening of arthritis; oral thrush; vaginal thrush; stomach cramps; fast/irregular heartbeat; frequent infections; swollen glands in neck/armpit/ groin; bleeding/bruising; blood in stool/poo; weakness of muscles; numbness/tingling/weakness of arms/legs; injection site reaction; impotence/persistent painful erection of penis, blurred blindness; loss of bladder control; new snoring; severe blisters and bleeding; itchy; allergic reaction; severe agitation/confusion; abnormal taste/sounds in the ears; heart attack; rapid/ shallow breathing; cold/clammy skin; a rapid/weak pulse; dizziness; weakness/fainting; yellowing of the whites of your eyes/skin; stroke; seizures/fits/convulsions; severe diarrhoea; kidney disease; blood in urine/pass little/no urine; notice any changes to skin colour or appearance;

have blisters that may have a discharge; skin peeling; experience any loss of sensation/numbness; coma. For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> effects? in the full CMI.

Bicillin® L-A

Active ingredient(s): benzathine benzylpenicillin

Consumer Medicine Information (CMI)

This leaflet provides important information about using Bicillin L-A. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Bicillin L-A.

Where to find information in this leaflet:

- 1. Why am I being treated with Bicillin L-A?
- 2. What should I know before treatment with Bicillin L-A?
- 3. What if I am taking other medicines?
- 4. How is Bicillin L-A given?
- 5. What should I know during treatment with Bicillin L-A?
- 6. Are there any side effects?
- 7. Product details

1. Why am I being treated with Bicillin L-A?

Bicillin L-A suspension for injection contains the active ingredient benzathine benzylpenicillin.

Benzathine benzylpenicillin is an antibiotic.

Bicillin L-A is used to treat the following infections:

- Mild-to-moderate infections of the upper respiratory tract caused by streptococci bacteria.
- Sexually transmitted infections such as syphilis, yaws, bejel and pinta.

Bicillin L-A is also used to prevent:

- The recurrence of rheumatic fever and chorea.
- Complications following rheumatic heart disease and severe kidney disease.

2. What should I know before treatment with Bicillin L-A?

Warnings

Do not use Bicillin L-A if:

- you are allergic to benzathine benzylpenicillin, or any of the ingredients listed at the end of this leaflet including lecithin (from soya bean) and benzoates.
- you have had previous allergic reactions to any penicillin medicines

If you are not sure if you are allergic to any of the above, ask your doctor.

Some of the symptoms of an allergic reaction may include rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or troubled breathing.

Check with your doctor if you:

- you have previous allergic reactions to penicillins or cephalosporins
- have or have had asthma, allergy, hay fever or skin problems
- have problems with your kidneys
- have had severe skin adverse reactions following antibiotic use
- have/had diarrhoea (or usually with blood and mucus, stomach pain, fever) following antibiotic use
- are on a sodium restricted diet as Bicillin L-A contains either 2.59 mg or 5.17 mg of sodium per injection, depending on the strength
- consider the symptoms of your infection have not improved within a few days, or if they have become worse

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

- Check with your doctor if you are pregnant or intend to become pregnant.
- Tell your doctor if you are breastfeeding or plan to breastfeed. Bicillin L-A may pass into breastmilk, your doctor can discuss the risks and benefits of treatment while breastfeeding.

Use in the elderly

The risk of toxic reactions may be increased in patients greater than 65 years of age who have kidney problems. Your doctor should monitor you carefully in this situation.

3. What if I am taking other medicines?

Tell your doctor, nurse or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Bicillin L-A, these include:

- Tetracyclines, a class of antibiotics that treat several kinds of bacterial infections, e,g, doxycycline and minocycline,
- Probenecid, a medicine used to treat chronic gout or gouty arthritis and may be used in HIV treatment

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Bicillin L-A.

4. How is Bicillin L-A given?

How much is given

 Your doctor will decide how much Bicillin L-A you should receive and the length of time for which you

should receive it based on what it is being used to treat and your age.

How is Bicillin L-A given

Bicillin L-A is given as an injection into deep muscle on your buttock (bottom cheek). For infants and children, it may be given in the middle front thigh. If injections must be repeated, they should not be given in exactly the same place each time.

If you use too much Bicillin L-A

As Bicillin L-A is given under the close supervision of your doctor, it is very unlikely that you will receive too much. If you experience any side effects, tell your doctor or nurse immediately.

Tell your doctor or nurse immediately if you are concerned that you may have been given too much Bicillin L-A. Or you should immediately phone the Poisons Information Centre (by calling 13 11 26).

5. What should I know during treatment with Bicillin L-A?

Things you should do

Keep all of your doctor's appointments and attend any tests as directed, as treatment with Bicillin L-A may require your doctor to monitor your kidneys and blood.

Tell your doctor or nurse straight away if you:

- do not experience an improvement of the symptoms of your infection within a few days, or if they become worse
- have any allergic reactions
- have flu-like symptoms including fever, sore throat and fatigue with severe skin problems such as a painful rash, blisters which may have pus or peeling
- have sores in the mouth, eyes, nose and genitals
- have redness and swelling of the eyes or conjunctivitis
- have swelling of the face
- experience any fungal or candida/thrush infections (sore, creamy-yellow, raised patches in the mouth or vaginal itching, burning with a thick, white, 'cottage cheese' discharge)
- have a rapid onset of weakness, pain, and numbness in the legs and/or arms, often with a bandlike tightness around the chest or stomach, and/or any problems when going to the toilet such as incontinence (with both urine/wee and poo) or inability to wee
- notice any changes to skin colour or appearance, especially on your fingers or toes such as turning red, brown, bronze, purple, blue, or black; have blisters that may have a discharge; peeling; or experience any loss of sensation or numbness
- paleness, mottling or a blue colour of the skin, or severe swelling around or near where the injection was given

 have diarrhoea (usually with blood and mucus) or stomach pain, even if it happens several weeks after treatment with Bicillin L-A has been stopped.

Remind any doctor, nurse, dentist or pharmacist who are treating you that you are being given Bicillin L-A.

Things you should not do

Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Bicillin L-A affects you.

Bicillin L-A may cause dizziness or visual disturbances in some people

Drinking alcohol

No information is available.

Looking after your medicine

Bicillin L-A is stored in the pharmacy, clinic or on the hospital ward under the correct conditions.

Disposal of Bicillin L-A

The hospital or clinic staff will dispose of any leftover Bicillin L-A.

6. Are there any side effects?

All medicines can have side effects. Some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects	What to do
 feeling anxious, nervous, abnormally happy or experience tremors 	Speak to your doctor if you have any of these side effects and they worry you.
sleepiness, tiredness or snoring	
 nausea or vomiting, headache 	
 excessive or abnormal sweating not caused by heat or exercise 	
 muscle, joint pain, pain or swelling along bones, worsening of arthritis oral thrush - white, furry, sore tongue and mouth 	
 vaginal thrush - sore and itchy vagina and / or vaginal discharge 	

Serious side effects that may require medical attention

What to do

- stomach cramps
- fast or irregular heartbeat
- frequent infections (symptoms such as fever, severe chills, sore throat or mouth ulcers)
- swollen glands in the neck, armpit or groin
- bleeding or bruising more easily than normal
- blood in stool/poo
- weakness of muscles
- numbness, tingling or weakness of the arms and legs
- injection site reaction, which may include pain, irritation, swelling, lump, redness, bruising or other change in colour, bleeding or ulceration
- impotence or persistent painful erection of the penis which occurs without sexual arousal

Speak to your doctor or nurse as soon as possible if you notice any of these side effects.

Serious side effects that may require medical attention	What to do
 blurred vision, blindness. loss of bladder control, not being able to empty or feel usual sensations with your bladder blurred vision, blindness. 	

Very serious side
effects. You may need
urgent medical attention
or hospitalisation You
may not experience any
of them.

What to do

- severe blisters and bleeding in the lips, eyes, mouth, nose or genitals
- itchy spots accompanied by fever and feeling unwell
- allergic reaction e.g. shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body,

Tell your doctor or nurse immediately, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Very serious side effects. You may need urgent medical attention or hospitalisation You may not experience any of them.

What to do

rash, itching or hives on the skin

- severe agitation, confusion and hallucinations, abnormal fear of impending death, abnormal taste or abnormal sounds in the ears
- heart attack, symptoms may include chest or shoulder pain, tightness of chest, shortness of breath
- rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting
- yellowing of the whites of your eyes or skin
- stroke (collapse, numbness or weakness of the arms or legs, headache, dizziness

Very serious side effects. You may need urgent medical attention or hospitalisation You may not experience any of them.

What to do

and confusion, visual disturbance, difficulty swallowing, slurred speech and loss of speech)

- seizures, fits or convulsions
- severe diarrhoea, usually with blood and mucus, stomach pain, fever. This may occur during treatment or several weeks after treatment with Bicillin L-A
- kidney disease, with blood in the urine or pass little or no urine
- notice any changes to skin colour or appearance, especially on your fingers or toes such as turning red, brown, bronze, purple, blue, or black; have

Very serious side effects. You may need urgent medical attention or hospitalisation You may not experience any of them.	What to do
blisters that may have a discharge; peeling; or experience any loss of sensation or numbness coma	
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Some people may get other side effects whilst receiving Bicillin L-A.

Do not take any diarrhoea medicine without first checking with your doctor. Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list

Some of these side effects (for example blood abnormalities) can only be found when your doctor does tests from time to time to check your progress.

Reporting side effects

After you have received medical advice for any side effects you may experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems By reporting side

effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Bicillin L-A contains

Active ingredient (main ingredient)	Benzathine benzylpenicillin tetrahydrate
Other ingredients	Sodium citrate
(inactive ingredients)	Water for injections
	Soya bean products (lecithin)
	Carmellose sodium
	Povidone
	Methyl hydroxybenzoate
	Propyl hydroxybenzoate
Potential allergens	Methyl hydroxybenzoate
	Propyl hydroxybenzoate

Soya bean products (lecithin)

Do not take this medicine if you are allergic to any of these ingredients.

Each Bicillin L-A contains benzathine benzylpenicillin tetrahydrate 442 mg/mL.

What Bicillin L-A looks like

Bicillin L-A is white fluid in a pre-filled glass syringe.

Aust R 147169, 293456

Who distributes Bicillin L-A

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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