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 taking LPV?

LPV contains the active ingredient, phenoxymethylpenicillin. LPV is used to treat infections in different parts of the body caused by certain bacteria.

For more information, see Section <u>1. Why am I taking</u> <u>LPV?</u> in the full CMI.

2. What should I know before I take LPV?

Do not take if you have ever had an allergic reaction to LPV or any of the ingredients listed at the end of the CMI or to any medicines containing phenoxymethylpenicillin, any other penicillins.

Talk to your doctor if you have any other medical conditions, are allergic to cephalosporin antibiotics, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section <u>2. What should I know</u> <u>before I take LPV?</u> in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LPV and affect how it works.

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

4. How do I take LPV?

- Your doctor will decide the best dose and how often you should take LPV.
- Follow your doctor's instructions and complete the full course of LPV prescribed by them.

More instructions can be found in Section <u>4. How do I</u> <u>take LPV?</u> in the full CMI.

5. What should I know while taking LPV?

Things you should do	 Tell your doctor immediately if your symptoms do not improve within a few days, become worse or you do not feel well while taking LPV
	 Tell your doctor immediately if you become pregnant while taking LPV

	 Remind any doctor, dentist or pharmacist you visit that you are taking LPV.
Things you should not do	 Do not stop taking LPV or change the dosage without checking with your doctor.
Driving or using machines	 Be careful driving or operating machinery until you know how LPV affects you.
Drinking alcohol	 Drinking alcohol while taking medicines is not recommended.
Looking after your medicine	 Store capsules below 25°C in a cool dry place. Keep out of reach of children

For more information, see Section <u>5. What should I know</u> while taking LPV? in the full CMI.

6. Are there any side effects?

Common side effects include diarrhoea, nausea, vomiting, stomach pain or fever or a black hairy tongue. Serious side effects include severe watery or bloody diarrhoea, and hypersensitivity and allergic reactions. For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

LPV®

Active ingredient: Phenoxymethylpenicillin

Consumer Medicine Information (CMI)

This leaflet provides important information about using LPV. 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 LPV.

Where to find information in this leaflet:

- 1. Why am I using [medicine name]?
- 2. What should I know before I use [medicine name]?
- 3. What if I am taking other medicines?
- 4. How do I use [medicine name]?
- 5. What should I know while using [medicine name]?
- 6. Are there any side effects?
- 7. Product details

1. Why am I taking LPV?

LPV contains the active ingredient,

phenoxymethylpenicillin. LPV is an antibiotic that belongs to a group of medicines called penicillins. These antibiotics work by killing the bacteria that are causing your infection.

LPV is used to treat infections in different parts of the body caused by certain bacteria.

LPV may also be used to prevent infections before, during and after surgery but will not work against infections caused by viruses, such as colds.

2. What should I know before I take LPV?

Warnings

Do not take LPV:

- If you are allergic to phenoxymethylpenicillin, any other penicillins or to any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:
- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin
- Always check the ingredients to make sure you can take LPV
- To treat any other medical conditions unless instructed by your doctor
- If the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- Have allergies to any medicines, and in particular to cephalosporin antibiotics, foods, preservatives or dyes
- Have previously had or currently have any health issues, such as asthma
- Have a potassium deficiency or have high potassium blood levels. Each LPV 250 mg capsule contains 28 mg potassium and each LPV 500 mg capsule contains 55 mg potassium.
- Take any medicines for any other condition.

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. Are there any side effects</u>?

Pregnancy and breastfeeding:

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will discuss the risks and benefits of taking LPV while pregnant and breastfeeding

3. What if I am taking other medicines?

Tell your doctor 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.

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

4. How do I take LPV?

How much to take:

- Your doctor will decide the best dose and how often you should take LPV.
- Follow your doctor's instructions and complete the full course prescribed by them, even if you begin to feel better after a few days. If you do not finish all your LPV, the bacteria causing your infection may not clear completely or your symptoms may return.
- Swallow the capsules whole with a glass of water.

When to take LPV:

• Take about one hour before food or two hours after food. It can be taken with food, but it may not be as effective.

If you forget to take LPV:

LPV should be taken regularly at the same time each day.

If you miss a dose and it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you take too much LPV:

If you think that you have taken too much LPV, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking LPV?

Things you should do:

Keep all of your doctor's appointments so that your progress can be checked.

Call your doctor straight away:

- If your symptoms do not improve within a few days, or become worse
- If you do not feel well while taking LPV
- If you experience any of the following, even if they occur several weeks after stopping treatment with LPV:
 - severe stomach cramps or pain
 - severe watery or bloody diarrhoea
 - with or without a fever

Do not take any diarrhoea medication without first checking with your doctor. You may have a serious condition affecting your bowel requiring urgent medical attention

• If you become pregnant while taking LPV.

Remind any doctor, dentist or pharmacist you visit that you are taking LPV, especially if they are about to prescribe any new medication for you.

Things you should not do:

- Do not take LPV to treat any other complaints unless your doctor tells you to
- Do not give your medicine to anyone else, even if they have the same condition as you
- Do not stop taking LPV or change the dosage without checking with your doctor. LPV must be taken for the full course as prescribed by your doctor. If you stop

taking LPV without completing the full course, your condition may worsen.

Driving or using machines:

Be careful before you drive or use any machines or tools until you know how LPV affects you.

LPV is not expected to affect your ability to drive or operate machinery. However, you should be careful with these activities until you know how LPV affects you.

Children should be careful riding bicycles or climbing on playground equipment until you know how LPV affects them.

Drinking alcohol:

Tell your doctor if you drink alcohol.

Drinking alcohol whilst taking medication is not recommended.

Looking after your medicine:

- Store below 25°C
- Store LPV in the blister pack until it is time to take them.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

• in the bathroom or near a sink, or

• in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine:

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, 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.

Less serious side effects:

Less serious side effects	What to do
Common side effects: Diarrhoea Nausea 	Speak to your doctor if you have any of these less serious side effects
VomitingStomach pain	and they worry you.
FeverBlack hairy tongue	

Less serious side effects	What to do
Other side effects:	
 Rash and itchiness Sore throat, difficulty swallowing and bringing up undigested food 	

Serious side effects:

Serious side effects	What to do
 Severe stomach cramps or pain Severe watery or bloody diarrhoea Fever (when associated with the above symptoms Sudden signs of allergy such as skin reactions, with swelling of the face, lips, tongue or other parts of the body Shortness of breath Wheezing or trouble breathing 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects:

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/reporting-problems</u>. 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 LPV 250 mg capsules contain:

Active ingredient (main ingredient)	Phenoxymethylpenicillin (as the potassium salt)
Other ingredients	Brilliant blue FCF
(inactive ingredients)	Carbon black
	Erythrosine
	Gelatin

	Magnesium stearate
	Opacode black A-10259
	Sunset yellow FCF
	Titanium dioxide
Potential allergens	None

What LPV 500 mg capsules contain:

Active ingredient (main ingredient)	Phenoxymethylpenicillin (as the potassium salt)
Other ingredients	Brilliant blue FCF
(inactive ingredients)	Erythrosine
	Gelatin
	Magnesium stearate
	Opacode black A-10259
	Sunset yellow FCF
	Titanium dioxide
Potential allergens	None

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

What does LPV looks like:

LPV 250 mg capsules: Opaque red cap and opaque grey body with "LPV250" printed in black ink on cap and body. They come in a blister pack of 50 capsules.

Registration number: AUST R 66510

LPV 500 mg capsules: Red opaque cap and pink body with "LPV500" printed in black ink on cap and body. They come in a blister pack of 50 capsules.

Registration number: AUST R 66511

Who distributes LPV:

iNova Pharmaceuticals (Australia) Pty Limited

Level 10, 12 Help Street

Chatswood NSW 2067

Tel: 1800 630 056

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