

# Ethambutol Lupin

## Consumer Medicine Information (CMI) summary

The [full CMI](#) 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 Ethambutol?

Ethambutol Lupin contains the active ingredient ethambutol hydrochloride. Ethambutol Lupin is used to treat all forms of tuberculosis (including tuberculosis of the lung, skin, genital tract, urinary tract, bone and joint, eye and the brain).

For more information, see Section [1. Why am I taking Ethambutol Lupin?](#) in the full CMI.

### 2. What should I know before I take Ethambutol Lupin?

Do not use if you have ever had an allergic reaction to ethambutol or any of the ingredients listed at the end of the CMI.

Do not use Ethambutol Lupin if you have sight problems, kidney or liver problems. **Talk to your doctor if you have any other medical conditions, 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 I take Ethambutol Lupin?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Ethambutol Lupin 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 do I take Ethambutol Lupin?

- Ethambutol Lupin tablets should be taken once every 24 hours with or without food, with a glass of water.
- The size of the dose to be taken will depend on whether you have previously received treatment for tuberculosis. It also depends on your bodyweight. Your doctor will calculate the dose you need and tell you how many tablets to take each day.

More instructions can be found in Section [4. How do I take Ethambutol Lupin?](#) in the full CMI.

### 5. What should I know while taking Ethambutol Lupin?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Ethambutol Lupin.</li><li>• If you become pregnant while taking Ethambutol Lupin, tell your doctor immediately.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly.</li><li>• Do not use Ethambutol Lupin to treat any other medical complaints unless told to by your doctor</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Ethambutol occasionally causes sight problems and may present symptoms which affect the ability to drive or use machinery. After taking your medicine you should not drive or use machinery until you know how Ethambutol Lupin affects you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store below 30°C.</li><li>• Keep Ethambutol Lupin tablets in a cool, dry place.</li><li>• Do not store it, or any other medicine, in a bathroom or near a sink.</li></ul>

For more information, see Section [5. What should I know while taking Ethambutol Lupin?](#) in the full CMI.

### 6. Are there any side effects?

Blurred vision (eye problems), abdominal pain, fever, vomiting, dizziness, headache may occur commonly.

Anaphylactoid reaction (severe allergic reaction characterised by difficulty in breathing, flushed appearance, agitation or an irregular heartbeat), Stevens-Johnson syndrome (characterised by a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and/or genitals), toxic epidermal necrolysis (severe skin peeling and blistering) are the serious side effects that may occur.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Ethambutol Lupin

Active ingredient(s): *ethambutol (as hydrochloride)*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Ethambutol Lupin. **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 Ethambutol Lupin.**

Where to find information in this leaflet:

- [1. Why am I taking Ethambutol Lupin?](#)
- [2. What should I know before I take Ethambutol Lupin?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take Ethambutol Lupin?](#)
- [5. What should I know while take Ethambutol Lupin?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I taking Ethambutol Lupin?

Ethambutol Lupin contains the active ingredient **ethambutol hydrochloride**. Ethambutol Lupin is an antibiotic that belongs to a group of medicines called antituberculosis drugs.

**Ethambutol Lupin is used to treat all forms of tuberculosis (including tuberculosis of the lung, skin, genital tract, urinary tract, bone and joint, eye and the brain).**

Your doctor may have prescribed Ethambutol Lupin for another purpose.

**Ask your doctor if you have any questions about why it has been prescribed for you.**

## 2. What should I know before I take Ethambutol Lupin?

### Warnings

Do not take Ethambutol Lupin if:

- you are allergic to ethambutol, or any of the ingredients listed at the end of this leaflet.** Some of the symptoms of an allergic reaction to ethambutol 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.

Always check the ingredients to make sure you can use this medicine.

**Check with your doctor if you:**

- have any other medical conditions including:
  - eye problems or feel your eyesight is being affected (for example, your vision becomes blurred);
  - kidney disease;
  - liver problems;
  - gout.
- 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 [6. Are there any side effects?](#)

## 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.

## 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.

**Some medicines may interfere with Ethambutol Lupin and affect how it works.**

**Medicines that may reduce the effect of Ethambutol Lupin include:**

- aluminium hydroxide (found in acid suppressing drugs or antacids).

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

## 4. How do I take Ethambutol Lupin?

### How much to take

- The size of the dose to be taken will depend on whether you have previously received treatment for tuberculosis. It also depends on your bodyweight.
- Ethambutol Lupin will be prescribed with other antituberculosis drugs. Your doctor will decide on the best combination of drugs for you to take.
- Follow the instructions provided when Ethambutol Lupin was prescribed, including the number of days it should be taken.

### Initial Treatment

- If you have not been treated for tuberculosis before, the usual dose is 15 mg/kg of bodyweight of

Ethambutol Lupin to be taken as a single dose once every 24 hours.

### Re-Treatment

- If you have been treated for tuberculosis before, the usual dose is 25 mg/kg of bodyweight of Ethambutol Lupin to be taken as a single dose, once every 24 hours. After 60 days the dose will be lowered to 15 mg/kg of bodyweight.
- These dosages may be changed by your doctor.
- Continue taking it until your doctor tells you to stop.

### When to take Ethambutol

- Ethambutol Lupin tablets should be taken once every 24 hours with or without food, with a glass of water.
- It can take up to 2 years of treatment with Ethambutol Lupin to cure you of tuberculosis. It is important that you keep taking the medicine for the full time of treatment.
- Do not stop taking it if you start feeling better. You must have regular checkups.
- If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

### If you forget to take Ethambutol Lupin

Ethambutol Lupin should be used regularly at the same time each day.

**If 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 are not sure what to do, ask your doctor or pharmacist.**

**If you have trouble remembering to take your medicine, ask your pharmacist for some hints.**

### If you take too much Ethambutol Lupin

If you think that you have used too much Ethambutol Lupin, 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 Ethambutol Lupin?

### Things you should do

- **If you are about to start taking any new medicines, tell your doctor or pharmacist that you are taking Ethambutol Lupin.**
- **If you become pregnant while taking Ethambutol Lupin, tell your doctor immediately.**

- **Only use Ethambutol Lupin at the times and doses recommended by your doctor.**

Remind any doctor, dentist or pharmacist you visit that you are using Ethambutol Lupin.

### Things you should not do

- Do not stop using this medicine suddenly.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not use Ethambutol Lupin to treat any other medical complaints unless told to by your doctor.

### Call your doctor straight away if you:

- **have had any deterioration in your eyesight or blurred vision since starting Ethambutol Lupin.** About 3% of patients treated with Ethambutol Lupin find that their vision becomes blurred. This effect however is generally reversible if the treatment is stopped promptly.
- **develop any skin rash such as spots or hives during Ethambutol Lupin treatment.** There are reports of rare, severe, potentially life-threatening rashes associated with Ethambutol Lupin treatment, particularly in children. These rashes may be from a condition such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) which can be fatal if not treated immediately.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Ethambutol Lupin affects you.**

Ethambutol Lupin occasionally causes sight problems and may present symptoms which affect the ability to drive or use machinery (eg. numbness or paraesthesia (abnormal sensation like pins and needles) of the furthest parts of your body, disorientation and possible hallucinations).

### Looking after your medicine

- Store below 30°C.

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 use 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
<ul style="list-style-type: none"><li>• Blurred vision.</li><li>• Allergic reactions.</li><li>• Dermatitis.</li><li>• Pain in the joints.</li><li>• Loss of appetite.</li><li>• Nausea.</li><li>• Vomiting.</li><li>• Upset stomach.</li><li>• Fever.</li><li>• Headache.</li><li>• Dizziness.</li><li>• Mental confusion.</li><li>• Disorientation.</li><li>• Possible worsening of gout.</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>• Disorientation.</li><li>• Possible hallucinations.</li><li>• Numbness and tingling in the feet and hands.</li><li>• Severe allergic reaction (eg. difficulty in breathing, flushed appearance, agitation or an irregular heartbeat).</li><li>• Stevens-Johnson syndrome (a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and/or genitals).</li><li>• Toxic epidermal necrolysis (severe skin peeling and blistering).</li><li>• skin rash such as spots or hives</li></ul>	<p><b>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.</b></p>

**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 [www.tga.gov.au/reporting-problems](http://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 Ethambutol Lupin contains

Active ingredient (main ingredient)	Ethambutol (as hydrochloride)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"><li>• Colloidal anhydrous silica</li><li>• Ethylcellulose</li><li>• Hypromellose</li><li>• Magnesium stearate</li><li>• Maize starch</li><li>• Polyethylene glycol monomethyl ether</li><li>• Povidone</li><li>• Propylene glycol</li><li>• Purified talc</li><li>• Titanium dioxide</li></ul>

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

### What Ethambutol Lupin looks like

Ethambutol Lupin 400 mg tablets are white to off white circular, biconvex, film-coated tablets, plain on both sides available in either blister pack (AUST R 365232) or HDPE bottle pack (AUST R 365231).

Not all packs may be marketed.

### Who distributes Ethambutol Lupin

Generic Health Pty Ltd

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19-23 Prospect Street

Box Hill, VIC, 3128

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