

Tolvaptan 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 using Tolvaptan Lupin?

Tolvaptan Lupin contains the active ingredient tolvaptan. Tolvaptan Lupin is used to treat a disease called Autosomal Dominant Polycystic Kidney Disease (ADPKD).

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

2. What should I know before I use Tolvaptan Lupin?

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

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

For more information, see Section [2. What should I know before I use Tolvaptan Lupin?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Tolvaptan 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 use Tolvaptan Lupin?

- Tolvaptan Lupin is to be taken in two different doses every day. Your doctor will decide the best suitable dose based on your condition and response.
- The dose combinations are 45 mg + 15 mg or 60 mg + 30 mg or 90 mg + 30 mg

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

5. What should I know while using Tolvaptan Lupin ?

| | |
|------------------------------------|---|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist, or you visit that you are using tolvaptan.• Make sure you drink plenty of water –MAKE SURE YOU DRINK ENOUGH WATER |
| Things you should not do | <ul style="list-style-type: none">• Do not stop using Tolvaptan Lupin or change the dosage without first discussing it with your doctor.• Do not take this medicine to treat any other complaints unless your doctor tells you to.• Do not give this medicine to anyone else, even if they have the same condition as you |
| Driving or using machines | <ul style="list-style-type: none">• Tolvaptan Lupin may cause side effects that can affect your ability to drive or use machines.• Tolvaptan Lupin may make you feel dizzy or sleepy, particularly at the beginning of treatment. If this happens to you, do not drive, or use any tools or machines. |
| Drinking alcohol | <ul style="list-style-type: none">• Tell your doctor if you drink alcohol. |
| Looking after your medicine | <ul style="list-style-type: none">• Keep your medicine in a cool dry place where the temperature stays below 25°C. |

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

6. Are there any side effects?

Common side effects include thirst; increased amount and frequency of urination; headache; constipation; diarrhoea; dry mouth; indigestion; decreased appetite; fatigue; weakness; dizziness; trouble sleeping; muscle spasms; rash; dry skin; itching; painful, swollen joints. Serious side effects include difficulty urinating; swelling of the face, lips or tongue; generalised rash; or severe wheezing or breathlessness; signs of electrolyte imbalances.

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.

Tolvaptan Lupin

Active ingredient: *tolvaptan*

WARNING: Tolvaptan Lupin can cause serious liver problems.

Stop taking Tolvaptan Lupin and call your healthcare provider right away if you get any of the following symptoms: feeling tired, fever, loss of appetite, rash, nausea, itching, right upper stomach (abdomen) pain or tenderness, yellowing of the skin and white part of the eye (jaundice), vomiting, dark urine.

To help reduce your risk of liver problems, your healthcare provider will ask you to do a blood test to check your liver before you start taking Tolvaptan Lupin – monthly for the first 18 months of treatment and then every 3 months.

It is important to stay under the care of your healthcare provider during treatment with Tolvaptan Lupin.

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Tolvaptan Lupin?

Tolvaptan Lupin contains the active ingredient tolvaptan. Tolvaptan Lupin is vasopressin antagonist. This means that it prevents a hormone called vasopressin from binding to receptors in your kidneys. By blocking the effect of vasopressin, Tolvaptan Lupin slows the development of kidney cysts in patients with Autosomal Dominant Polycystic Kidney Disease (ADPKD), reduces symptoms of the disease and increases urine production.

Tolvaptan Lupin is used to treat a disease called Autosomal Dominant Polycystic Kidney Disease (ADPKD). This disease causes growth of cysts in the kidneys which results in problems because of their size and the space they occupy.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Tolvaptan Lupin is not recommended for use in children and teenagers, or patients older than 55 years. The effects of Tolvaptan Lupin in people younger than 18 years had

not been studied, and in patients older than 55 years has not been proven.

2. What should I know before I use Tolvaptan Lupin?

Warnings

Do not use Tolvaptan Lupin if:

- you are allergic to tolvaptan, benzazepine derivative, or any of the ingredients listed at the end of this leaflet.
Always check the ingredients to make sure you can use this medicine.
- you have been told that you have raised levels of liver enzymes in your blood.
- you have high level of sodium in your blood ("hyponatraemia").
- you do not realise when you are thirsty.
- your kidneys cannot produce urine.
- you have low blood volume.
- you are pregnant.
- you are breastfeeding.
- you are below the age of 18 years. Safety and effectiveness in children younger than 18 years have not been established.

Check with your doctor if you:

- have, or have had, any other medical conditions, including if you:
 - suffer from liver disease;
 - suffer from too high or too low blood sodium;
 - suffer from high potassium levels in your blood;
 - have diabetes;
 - have high blood pressure and are taking medications to treat it;
 - have gout;
 - have lactose intolerance.

- cannot drink enough water or if you are fluid restricted;
- have difficulties in urination or have an enlarged prostate;
- are dehydrated or suffer from excessive vomiting, diarrhoea or sweating;
- 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.

Tolvaptan Lupin must not be taken if you are pregnant.

You must use a reliable method of contraception to avoid becoming pregnant while you are taking Tolvaptan Lupin. You should continue doing this for one month after stopping treatment.

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

Tolvaptan Lupin must not be taken if you are breastfeeding.

If you have not told your doctor about any of the above, tell them before you start taking Tolvaptan Lupin.

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 Tolvaptan Lupin and affect how it works.

In particular let your doctor know if you are taking:

- treatments containing ketoconazole, fluconazole or itraconazole for fungal infections;
- antibiotics, such as clarithromycin, erythromycin, and ciprofloxacin;
- rifampicin, an antibiotic;
- medicines for the treatment of HIV, such as saquinavir, ritonavir and atazanavir;
- medicines for high blood pressure and chest pain, such as diltiazem and verapamil;
- medicines which increase the level of sodium in your blood or which contain large amounts of salt, like tablets that dissolve in water and indigestion remedies;
- digoxin, a medicine for the treatment of irregular heartbeat and heart failure;
- cyclosporin, a medicine that reduces the immune response;
- quinidine, a medicine used for malaria;
- dabigatran, a medicine used to thin the blood;
- rosuvastatin and pitavastatin, medicines used to lower cholesterol;

- methotrexate, a medicine used to treat rheumatoid arthritis;
- sulfasalazine, a medicine used to treat inflammatory bowel disease;
- metformin, a medicine for diabetes;
- medicines for the treatment of epilepsy, such as phenytoin and carbamazepine;
- St John's Wort, a traditional herbal medicinal product for the relief of slightly low mood and mild anxiety;
- fluid tablets and other medicines used for the treatment of high blood pressure;
- desmopressin, a medicine used to control urine output or bedwetting.

It may still be alright for you to take these medicines and Tolvaptan Lupin together. Your doctor will be able to decide what is suitable for you.

Tolvaptan Lupin with food and drink

Do not drink grapefruit juice when taking Tolvaptan Lupin.

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

4. How do I use Tolvaptan Lupin?

How much to take

- Tolvaptan Lupin is to be taken in two different doses every day. The dose combinations are 45 mg + 15 mg or 60 mg + 30 mg or 90 mg + 30 mg.
- One tablet of the higher dose (45 mg, 60 mg or 90 mg) should be taken in the morning upon waking, at least 30 minutes before food, and one tablet with the lower dose (15 mg or 30 mg) should be taken 8 hours later. The afternoon dose can be taken with or without food.
- Your doctor will start with a dose combination of 45 mg in the morning and 15 mg 8 hours later and may then increase it to a maximum of 90 mg in the morning and 30 mg after 8 hours.
- To find the best dosage for you your doctor will regularly examine whether you tolerate a prescribed dose. You should always take the highest tolerable dose combination prescribed by your doctor.
- If you take other medicines which can increase the effects of Tolvaptan Lupin you may receive lower Tolvaptan Lupin doses.
- Your doctor may have prescribed a different dose.
- Follow the instructions provided and use Tolvaptan Lupin until your doctor tells you to stop.

When to take Tolvaptan Lupin

- Tolvaptan Lupin should be taken at about the same time each day.
- Taking it at the same time each day will have the best effect. It will also help you remember when to take it.
- Your first dose should be taken in the morning and your second dose approximately 8 hours later.

How to take Tolvaptan Lupin

- Swallow the tablets without chewing, with a glass of water.
- The morning dose should be taken at least 30 minutes before the morning meal. The second daily dose can be taken with or without food.
- Do not chew, crush or split the tablets. To ensure you get the entire dose, the tablets should be swallowed whole without chewing or crushing.

If you forget to use Tolvaptan Lupin

Tolvaptan Lupin should be taken regularly at the same time each day. If you miss your dose at the usual time you should take the dose as soon as you remember on the same 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 use too much Tolvaptan Lupin

If you think that you have used too much Tolvaptan 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 using Tolvaptan Lupin?

Things you should do

MAKE SURE YOU DRINK ENOUGH WATER

- Tolvaptan causes water loss because it increases your urine production. You may experience urine loss of between 5-7 litres per day.
- This water loss may result in side effects such as dry mouth and thirst or even more severe side effects like kidney problems (see additional information under [Section 6. Are there any side effects?](#)). It is therefore important that you have access to water and that you are able to drink sufficient amounts when you feel thirsty.
- Unless your doctor tells you otherwise, drink plenty of water during the day and 1 or 2 glasses before going to bed, even if you do not feel thirsty. You must also drink water after you urinate at night.

- Exposure to prolonged heat and humidity, exercise and intercurrent illness can further increase your risk of dehydration. In these circumstances, you should drink more water or fluid to reduce your risk of dehydration.
- Special care must be taken if you have a disease that reduces appropriate fluid intake or if you are at an increased risk of water loss, eg. in case of vomiting or diarrhoea. If this occurs stop your tolvaptan treatment and seek medical advice immediately.
- Due to the increased urine production, it is also important that you always have access to a toilet.

Call your doctor straight away if you:

- become pregnant while taking Tolvaptan Lupin. Your doctor will advise you on whether you should stop treatment. Do not stop treatment without first discussing it with your doctor.

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking Tolvaptan Lupin. It may affect other medicines used during surgery.

If you are about to have any blood tests, tell your doctor that you are taking Tolvaptan Lupin. It may interfere with the results of some tests.

During treatment with Tolvaptan Lupin, your doctor will arrange regular (eg. monthly) blood tests to check for changes in your liver function.

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

Things you should not do

- Do not take Tolvaptan Lupin 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 your medicine or lower the dosage without checking with your doctor.

Your doctor will carefully observe you when you start Tolvaptan Lupin, especially when your dose is being increased.

Driving or using machines

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

Tolvaptan Lupin may cause side effects that can affect your ability to drive or use machines.

Tolvaptan Lupin may cause dizziness and sleepiness in some people, particularly at the beginning of treatment. If this happens to you, do not drive or use any tools or machines.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Store in a cool dry place where the temperature stays below 25°C.
- Keep your medicine in the original container. If you take it out of its original container it may not keep well.

Follow the instructions on 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 |
|---|---|
| <p>General well-being related:</p> <ul style="list-style-type: none">• Thirst.• Headache.• Fatigue, weakness, dizziness.• Trouble sleeping.• Muscle spasms. <p>Bladder related:</p> <ul style="list-style-type: none">• Increased amount of urine.• Increased frequency of urination during the day and at night. <p>Gastrointestinal related:</p> <ul style="list-style-type: none">• Constipation.• Diarrhoea.• Dry mouth.• Indigestion.• Decreased appetite. <p>Allergy related:</p> <ul style="list-style-type: none">• Rash.• Dry skin.• Itching. | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |

Pain related:

- Painful, swollen joints.

Serious side effects

| Serious side effects | What to do |
|---|--|
| <p>Bladder related:</p> <ul style="list-style-type: none">• Difficulty in urination. <p>Allergy related:</p> <ul style="list-style-type: none">• Symptoms of an allergic reaction such as swelling of the face, lips or tongue, itching, generalised rash, or severe wheezing or breathlessness. <p>General well-being related:</p> <ul style="list-style-type: none">• Signs of electrolytes imbalances such as dizziness, confusion, weakness, seizures, or palpitation. | <p>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.</p> |

Tolvaptan Lupin may cause your liver to not work properly. Therefore, please inform your doctor immediately if you have any signs that could indicate potential liver problems, such as:

- nausea;
- vomiting;
- fever;
- tiredness;
- loss of appetite;
- pain in the abdomen;
- dark urine;
- jaundice (yellowing of the skin or eyes);
- itching of your skin;
- joint and muscle pain with fever;

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. 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 Tolvaptan Lupin contains

| | |
|---|--|
| Active ingredient (main ingredient) | Tolvaptan |
| Other ingredients (inactive ingredients) | Lactose monohydrate Maize starch Microcrystalline cellulose Hyprolose Magnesium stearate Ferric oxide |
| Potential allergens | Lactose monohydrate |

This leaflet was prepared in October 2024.

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

What Tolvaptan Lupin looks like

Tolvaptan Lupin 15 mg is a pink to light pink coloured, capsule-shaped, mottled tablet debossed with “FO5” on one side and “LU” on other side.

Tolvaptan Lupin 30 mg is a pink to light pink coloured, round, flat-faced, bevelled edged, mottled tablet debossed with “FO6” on one side and “LU” on other side.

Tolvaptan Lupin 45 mg is a pink to light pink coloured, octagonal-shaped, mottled tablet debossed with “FO7” on one side and “LU” on other side.

Tolvaptan Lupin 60 mg is a pink to light pink coloured, almond-shaped, flat-faced, bevelled edged, mottled tablet debossed with “FO8” on one side and “LU” on other side

Tolvaptan Lupin 90 mg is a pink to light pink coloured, capsule-shaped, biconvex, mottled tablet debossed with “FO9” on one side and “LU” on other side

Australian Registration Numbers

Tolvaptan Lupin 15 mg: AUST R 417522

Tolvaptan Lupin 30 mg: AUST R 417527

Tolvaptan Lupin 15 mg + 45 mg combination pack: AUST R 417526

Tolvaptan Lupin 30 mg + 60 mg combination pack: AUST R 417521

Tolvaptan Lupin 30 mg + 90 mg combination pack: AUST R 417524.

Who distributes Tolvaptan Lupin

Generic Health Pty Ltd

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Australia

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