



## **Patient Guide**

# TOLVAPTAN LUPIN

(tolvaptan tablets)

Contents

About This Guide..... 3

How Tolvaptan Lupin Works in People with ADPKD and the Relationship Between Cysts, Kidney Size and Kidney Function in ADPKD..... 4

ADPKD & the Role of Vasopressin in Cyst Growth ..... 5

Tolvaptan Lupin and Vasopressin..... 5

Before Starting Tolvaptan Lupin ..... 6

    Required Blood Testing.....6

    Program Materials.....6

Steps for Starting Tolvaptan Lupin.....7

Important information to Know Before Starting Tolvaptan Lupin ..... 8

Pregnancy and Breastfeeding ..... 9

Information to Share With Your Healthcare Team .....10

Taking Tolvaptan Lupin ..... 11

    Tolvaptan Lupin Dosing .....11

    Tolvaptan Lupin Dose Combinations .....11

    How to take Tolvaptan Lupin ..... 12

    Missed Doses..... 12

    If You Take Too Much..... 12

    How to Store Tolvaptan Lupin..... 12

    Other Important Information..... 12

Importance of Adherence.....13

Water Intake and Elimination (urination) .....13

    Water Intake ..... 13

    Water Elimination (urination)..... 13

Other Potential Side Effects.....14

Important Tips to Remember.....14

More Information.....15



About This Guide

This guide provides you with important information to support you while taking Tolvaptan Lupin (tolvaptan tablets). This guide will help you to:

- understand the role of Tolvaptan Lupin in autosomal dominant polycystic kidney disease (ADPKD).
- take Tolvaptan Lupin as prescribed.
- recognise potential side effects of treatment.
- complete your regular monitoring appointments as required.

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.

This guide is only intended for patients who have been prescribed Tolvaptan Lupin for autosomal dominant polycystic kidney disease (ADPKD) and should be read in conjunction with the Consumer Medicine Information (CMI). This guide is not intended to replace professional medical advice. Should you require further information about Tolvaptan Lupin or ADPKD, please speak with your healthcare team.

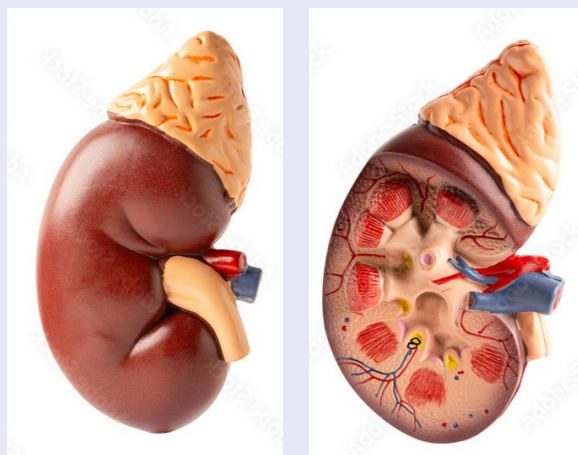
This guide is also available from Generic Health’s website: [www.generichealth.com.au](http://www.generichealth.com.au).

## How Tolvaptan Lupin Works in People with ADPKD and the Relationship Between Cysts, Kidney Size and Kidney Function in ADPKD

ADPKD is a common inherited kidney disease. In ADPKD, cysts (sacs filled with fluid) form in the kidney. When this happens, the affected parts of the kidney are often no longer able to function properly.

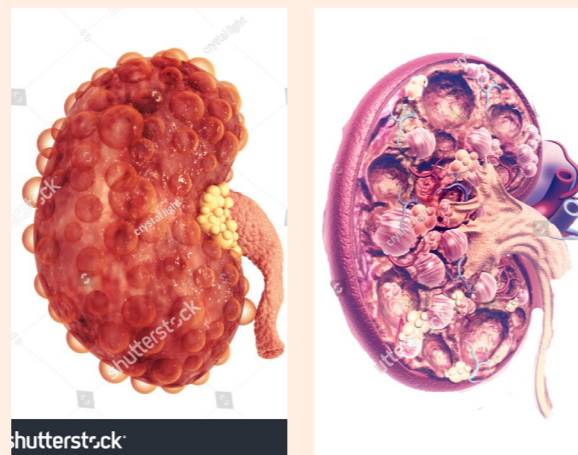
In ADPKD, cysts usually develop on both kidneys. Over time, more cysts develop, individual cysts get bigger, and some will eventually burst. Some people experience symptoms of disease progression, such as kidney pain.

If you have ADPKD, cysts on your kidneys keep developing and forming even if you do not have any symptoms yet. As the cysts continue to grow in number and size, the kidneys get larger and have a harder time doing their job. Eventually, they may stop working altogether.



### Healthy Kidneys

- No cysts or very few
- Tubules are open to drain urine into the bladder (through ducts)
- Kidneys are about the size of a fist

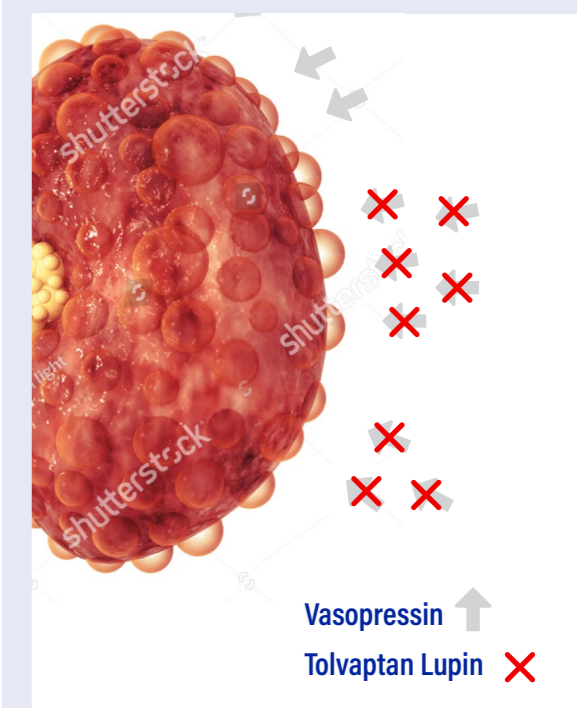


### Kidneys with ADPKD

- Cysts develop throughout the kidney; they increase in number and size as disease progresses
- Some tubules are blocked by cysts
- Kidneys get larger as disease progresses

## ADPKD & the Role of Vasopressin in Cyst Growth

To filter waste and water out of your blood, your kidneys use a hormone called vasopressin. Vasopressin makes the kidneys retain water. Vasopressin levels are higher than normal in people with ADPKD. The high level of vasopressin in people with ADPKD promotes cyst growth, which increases the size of the kidneys.



## Tolvaptan Lupin and Vasopressin

Tolvaptan Lupin is a medicine used for the treatment of ADPKD and works by blocking the effects of vasopressin. By blocking vasopressin, Tolvaptan Lupin should help slow down the rate at which cyst grow.

Because of the way that Tolvaptan Lupin works, you may produce more urine causing you to urinate more frequently during the day and night. This may become less pronounced over time, however speak with your healthcare team for advice on how to manage this effect.

# Before Starting Tolvaptan Lupin

Some patients taking Tolvaptan Lupin have experienced changes in liver function that could be a sign of a liver injury. To reduce the risk, regular blood tests are required before starting, and during treatment with, Tolvaptan Lupin. Your doctor will discuss all the potential risks and benefits of Tolvaptan Lupin with you before you are prescribed Tolvaptan Lupin.

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 as soon as possible if you do not feel well while you are taking Tolvaptan Lupin.

## Required Blood Testing

When	Frequency of Blood Tests
Prior to starting the treatment	Once
During first 18 months of treatment	Monthly
After 18 months of treatment	Every 3 months

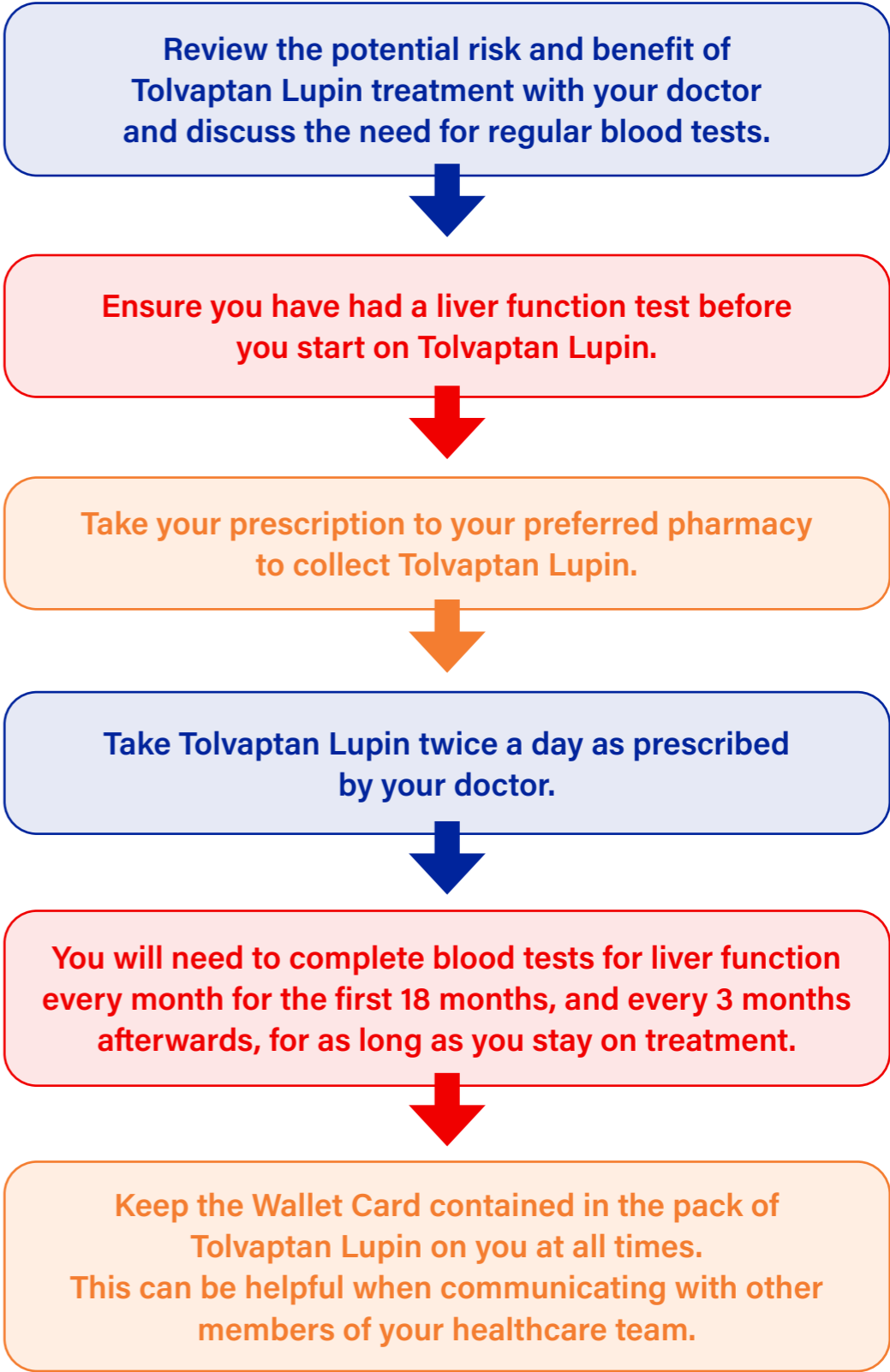
## Program Materials

Your doctor will provide you with a resource kit, which includes:

- this Patient Guide;
- the Tolvaptan Lupin Consumer Medicine Information (CMI); and
- the Tolvaptan Lupin Wallet Card. You should carry this Wallet Card with you at all times to alert other members of your healthcare team about your treatment with Tolvaptan Lupin.

Your doctor will also provide you with a prescription for Tolvaptan Lupin and with blood test request forms to check your liver function while you receive treatment.

# Steps for Starting Tolvaptan Lupin



## Important information to Know Before Starting Tolvaptan Lupin

### Do not use Tolvaptan Lupin if:

- you are allergic to tolvaptan, benzazepine derivatives or any of the ingredients listed in the CMI under 'Product Description'.
- you have been told that you have raised levels of liver enzymes in your blood.
- you have high levels of sodium in your blood.
- 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.

### Before starting Tolvaptan Lupin, check with your doctor if you:

- have any other medical conditions.
- take any medicines for any other condition.
- cannot drink enough water or are fluid restricted.
- are dehydrated or suffer from excessive vomiting, diarrhoea or sweating.
- have difficulty in urination or have an enlarged prostate.
- 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.
- are pregnant or breastfeeding.
- have lactose intolerance.

## Pregnancy and Breastfeeding

### Before and while taking Tolvaptan Lupin:

- tell your doctor if you are pregnant, plan to become pregnant or are breastfeeding. Tolvaptan Lupin is not recommended in pregnancy or while breastfeeding.
- tell your doctor immediately if you become pregnant. Your doctor will advise you on whether you should stop treatment.
- use a reliable method of contraception to avoid becoming pregnant. You should continue doing this for one month after stopping treatment.
- speak to your doctor about the appropriate contraceptive method for you. There are a number of different methods and it is important to choose one that best meets your needs and circumstances.



# Information to Share With Your Healthcare Team

## You should:

- tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. In particular, let your doctor know if you are taking any of the medications listed in the 'What if I am taking other medicines?' section of the CMI. 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.
- Tell any other doctors, dentists and pharmacists who treat you that you are taking Tolvaptan Lupin.
- Tell any surgeon or anaesthetist that you are taking Tolvaptan Lupin if you are going to have surgery.
- Tell your doctor if you drink alcohol.

Refer to the CMI for other information you should know while you are taking Tolvaptan



## Taking Tolvaptan Lupin

While you are taking Tolvaptan Lupin, you should follow all directions given to you by your healthcare team carefully. They may differ from the information contained in this guide.

### Tolvaptan Lupin Dosing

Tolvaptan Lupin is taken twice a day. Each Tolvaptan Lupin tablet has a different amount of medicine. The two tablets you take each day add up to your total daily dose. The first dose of the day is always higher than the second dose. This gives you the best balance between the amount of medicine in your body and possible increased urination at night.

Your doctor will prescribe one of three total daily doses shown in the table below. Your doctor may adjust your dose in the first weeks or months of treatment to help to find best dose for you. Take your prescribed dose as shown - however, if you take other medicines that increase the effects of Tolvaptan Lupin, your doctor may prescribe you a lower dose than shown below.

### Tolvaptan Lupin Dose Combinations

Total Daily Dose Your doctor will decide which dose is right for you	First Daily Dose Take upon waking and at least 30 minutes before eating	Second Daily Dose Take 8 hours after first daily dose with or without food
60 mg	45 mg	15 mg
90 mg	60 mg	30 mg
120 mg	90 mg	30 mg

## How to take Tolvaptan Lupin

When taking Tolvaptan Lupin you should:

- ✓ swallow the tablets whole with a glass of water, without splitting, chewing or crushing the tablets.
- ✓ take the first daily dose at least 30 minutes before eating.
- ✓ take the second daily dose approximately 8 hours after the first daily dose, with or without food.
- ✓ take your medicine at about the same time each day.
- ✓ drink plenty of water
- ✗ do not drink grapefruit juice while you are on treatment with Tolvaptan Lupin.

## Missed Doses

If you forget to take your medicine you should take the dose as soon as you remember on the same day. If you do not take any of your tablets on one day, take your normal dose on the next day.

**DO NOT take a double dose to make up for forgotten individual doses.**

## If You Take Too Much

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Tolvaptan Lupin. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

## How to Store Tolvaptan Lupin

Keep Tolvaptan Lupin in a cool, dry place where the temperature stays below 25°C. Keep it where young children cannot reach it.

## Other Important Information

Do not give your medicine to anyone else, even if they have the same condition as you.

## Importance of Adherence

**While taking Tolvaptan Lupin, it is important that you:**

- continue taking your medicine for as long as your doctor tells you.
- do not stop taking your medicine unless your doctor advises you to.
- do not change the dose without checking with your doctor.
- speak with your healthcare team for help to stay on treatment, especially if the effects of thirst and/or urination are causing you problems.
- do not take Tolvaptan Lupin to treat any other complaints unless your doctor tells you to.

## Water Intake and Elimination (urination)

### Water Intake

As an ADPKD patient, you may already know that it is important to drink plenty of water every day. This is also extremely important when you are on Tolvaptan Lupin. Water loss may result in side effects such as dry mouth and thirst or even more severe side effects like kidney problems. It is therefore important that you have access to water and that you are able to drink sufficient amounts when you feel thirsty.

To prevent dehydration, make sure you have water available to drink at all times while you are on Tolvaptan Lupin. Unless your healthcare team tells you otherwise, you should:

- ✓ drink plenty of water during the day or in response to thirst.
- ✓ drink 1-2 glasses of water before bedtime, even if you are not thirsty.
- ✓ drink water after you urinate at night.

Certain medicines or illnesses may keep you from drinking fluids or may cause you to lose too much body fluid such as excessive vomiting, diarrhoea or sweating. If you have these problems, call your healthcare team right away.

### Water Elimination (urination)

Because of the way Tolvaptan Lupin works, you are likely to experience thirst, an increased amount of urine and/or increased frequency of urination, including at night. Tolvaptan Lupin can cause approximately 5-7 litres of urine to be produced per day. Talk to your healthcare team to understand how to best manage these side effects, if you have them.

## Other Potential Side Effects

Tolvaptan Lupin, like any other medicine, can have side effects. Sometimes they are serious, most of the time they are not. Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Tolvaptan Lupin. For more information on the potential side effects of this medication, please read the CMI or speak with your healthcare team.

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, itching skin; painful, swollen joints.

Serious side effects include: difficulty urinating; swelling of the face, lips or tongue; generalised rash; severe wheezing or breathlessness; signs of electrolyte imbalances.

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.

## Important Tips to Remember

- It's best to continue using the same pharmacy as Tolvaptan Lupin is a specialty product, and the pharmacist can make sure Tolvaptan Lupin is available when you need it.
- Complete your blood tests for liver function monthly for the first 18 months, and then every 3 months thereafter.
- If your blood test results are normal, place your Tolvaptan Lupin order with your preferred pharmacy.
- If your blood test results are abnormal, your doctor will contact you to discuss your treatment plan.
- A Wallet Card is provided to identify that you are on Tolvaptan Lupin and can be helpful when communicating with other members of your healthcare team.

## More Information

### For more information on Tolvaptan Lupin:

- If you require more information about your disease or Tolvaptan Lupin treatment, please speak with your healthcare team.
- Read the Tolvaptan Lupin CMI available at [www.generichealth.com.au](http://www.generichealth.com.au) or call the Generic Health Medical Information team at the details below.

### For further information, please contact the Generic Health Medical Information team:

- by phone at **03 9809 7900, option 2**; or
- by email at **ghinfo@generichealth.com.au**.



