

PATIENT INFORMATION BROCHURE

Your guide to understand,
begin and continue treatment with

Pr LUPIN-TOLVAPTAN FOR AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE (ADPKD)

LUPIN GENESIS
PATIENT SUPPORT PROGRAM

YOUR GUIDE TO GET STARTED WITH LUPIN-TOLVAPTAN

This brochure is for people with Autosomal Dominant Polycystic Kidney Disease (ADPKD) who have been prescribed LUPIN-TOLVAPTAN. It will help you understand and discuss the potential benefits and risks of tolvaptan with your doctor. It will also help you understand how LUPIN-TOLVAPTAN works, how it should be taken and possible side effects that may occur during the treatment.

The information in this brochure does not replace the advice of your prescriber. Discuss your disease, your treatment, and any questions you have with your doctor.

If you are new to LUPIN-TOLVAPTAN

Please take a few moments to read through this guide and write down any questions you may have for your healthcare team.

If you are transitioning to LUPIN-TOLVAPTAN, a lower-cost generic alternative, from another tolvaptan product

A generic alternative is a copy of a brand name drug. The generic alternative is pharmaceutically equivalent to the brand name drug: it contains the identical medicinal ingredients, in the same amounts and in a similar dosage form.

A generic alternative is made to act in the same way in the body as the brand name drug and has the same safety and efficacy. Generic versions of brand name drugs are usually available at a lower cost. LUPIN-TOLVAPTAN meets all the same safety and efficacy criteria as the brand name drug and Health Canada has approved it as interchangeable.

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How LUPIN-TOLVAPTAN works in ADPKD patients

What is ADPKD?

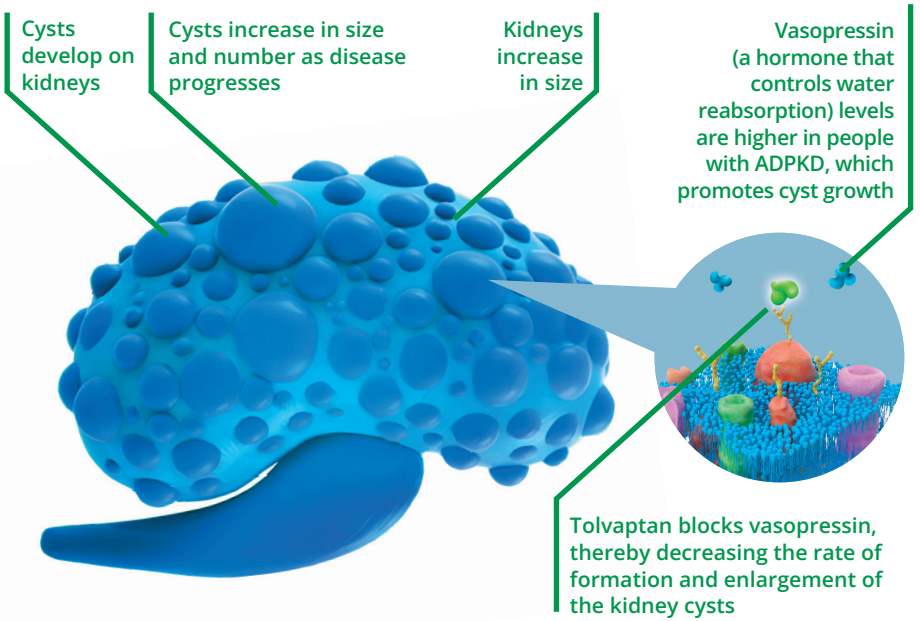
ADPKD is a genetic disorder which leads to the growth of multiple cysts (sacs filled with fluid) on the kidneys. Over time, the cysts grow in size, which can damage the way your kidneys work, and may ultimately lead to kidney failure.

How does LUPIN-TOLVAPTAN work?

LUPIN-TOLVAPTAN slows cyst growth and the decline of kidney function, which can help protect the kidneys from damage and failure.

LUPIN-TOLVAPTAN works by blocking the effects of a hormone called vasopressin, which promotes cyst growth on the kidneys in patients with ADPKD. By blocking the effects of the hormone, LUPIN-TOLVAPTAN is able to reduce the growth of the cysts on the kidneys and slow the decline of kidney function. This should help protect your kidneys from damage and failure.

Because of the way that LUPIN-TOLVAPTAN works, you will produce more urine, causing you to urinate more frequently during the day and at night. This may become less pronounced over time.

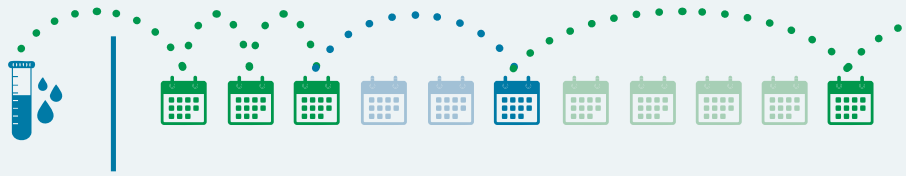


Before you start LUPIN-TOLVAPTAN

Before taking LUPIN-TOLVAPTAN you should discuss carefully with your doctor if this medication is suitable for you, taking into consideration the potential benefits and risks involved. In rare cases, tolvaptan patients have experienced changes in liver function that could, if left untreated, cause liver injury. To reduce this risk, you must agree to get regular blood tests, and you must enroll in the Lupin Genesis program. Once you and your doctor have agreed that LUPIN-TOLVAPTAN is suitable for you, your doctor will ask that you sign a consolidated Patient-Prescriber Agreement Form (PPAF) enrollment form, stating that you understand the benefits and risks of treatment and that you agree to take blood tests as prescribed by your doctor to start and remain on treatment.

During treatment with LUPIN-TOLVAPTAN, your doctor will arrange blood tests to check for changes in your liver function, as follows:

Before starting treatment with LUPIN-TOLVAPTAN	Every month for the first 18 months	Every 3 months for the next 12 months	Every 3–6 months thereafter during treatment



The Lupin Genesis program can remind you when it's time to get your blood test done. This is important, because your doctor will need to review your blood test results and provide their approval before you can receive your next refill of LUPIN-TOLVAPTAN.

Your doctor will discuss the Lupin Genesis program with you before you are prescribed LUPIN-TOLVAPTAN.

Confirming your understanding: The consolidated Patient-Prescriber Agreement Form (PPAF) enrollment form

Your doctor will review all the potential risks and benefits of LUPIN-TOLVAPTAN with you before prescribing LUPIN-TOLVAPTAN. If you both agree that LUPIN-TOLVAPTAN is suitable for you, you and your doctor must co-sign the consolidated PPAF enrollment form.

Signing the consolidated PPAF enrollment form means that you:

- understand the potential risks, especially for the liver, and the benefits that may occur over time when receiving treatment with LUPIN-TOLVAPTAN
- agree to undergo your regular blood tests
- agree to being treated with LUPIN-TOLVAPTAN

A new consolidated PPAF enrollment form is required if your physician (prescriber) or brand of tolvaptan changes.



You should not take LUPIN-TOLVAPTAN if:

- you have been asked to permanently discontinue tolvaptan in the past.
- you are allergic to tolvaptan, benzazepine or benzazepine derivatives (e.g., REMERON®), or any non-medicinal ingredients in the formulation.
- you cannot replace fluids by drinking or you cannot feel if you are thirsty.
- you have elevated sodium (salt) in your blood.
- you have a condition associated with a low blood volume.
- your liver is not functioning properly and in a way that is of concern to your doctor. The presence of hepatic cysts in and of themselves should not be an impediment to initiation of LUPIN-TOLVAPTAN treatment.
- you are pregnant or plan to become pregnant. It is not known if LUPIN-TOLVAPTAN will harm your unborn baby.
- you are breast-feeding. It is not known if LUPIN-TOLVAPTAN passes into your breast milk. You and your healthcare provider should decide if you will take LUPIN-TOLVAPTAN or breast-feed. You should not do both.
- your body is not able to make any urine. LUPIN-TOLVAPTAN will not help your condition.
- you take certain medicines. These medicines could cause you to have too much LUPIN-TOLVAPTAN in your blood:
  - the antibiotic medicines clarithromycin or telithromycin
  - the antifungal medicines ketoconazole or itraconazole
  - the anti-HIV medicines ritonavir, indinavir, nelfinavir, and saquinavir
  - the antidepressant medicine, nefazodone
- you have one of the following rare hereditary diseases:
  - Galactose intolerance
  - Lapp lactase deficiency
  - Glucose-galactose malabsorption

  because lactose is a non-medicinal ingredient in LUPIN-TOLVAPTAN.

Pregnancy prevention

To prevent pregnancy while on LUPIN-TOLVAPTAN treatment, women of childbearing potential must have effective contraceptive measures in place before and during treatment.

LUPIN-TOLVAPTAN and other medicines

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines. Taking LUPIN-TOLVAPTAN with other medicines may affect the way LUPIN-TOLVAPTAN works, or the way other medicines work. Your doctor may need to adjust your dose of LUPIN-TOLVAPTAN or of the other drugs if you take them together.

The following medicines may interact with LUPIN-TOLVAPTAN: clarithromycin, ketoconazole, ritonavir, saquinavir, rifampicin, phenytoin, carbamazepine, St. John's Wort, cyclosporin, quinidine, verapamil, erythromycin, fluconazole, hypertonic saline solutions, drugs that increase serum sodium concentrations, drugs known to increase serum potassium levels (such as spironolactone), digoxin, consuming grapefruit juice, or vasopressin drugs, such as desmopressin, used to control bleeding.

Always take LUPIN-TOLVAPTAN exactly as your doctor has prescribed. Check with your doctor, nurse or pharmacist if you are not sure.

You can take LUPIN-TOLVAPTAN with or without food.

While taking LUPIN-TOLVAPTAN you will produce more urine, urinate more frequently, and urinate at night. If this causes you concern, consult your doctor, nurse or pharmacist. This side effect should become less pronounced with time.

To prevent becoming dehydrated, have water available to drink at all times while taking LUPIN-TOLVAPTAN. Unless your doctor tells you otherwise, drink plenty of water during the day and one or two glasses before going to bed. If you suffer from vomiting, diarrhea or any other condition that might cause you to become dehydrated while taking LUPIN-TOLVAPTAN, call your doctor.

Taking LUPIN-TOLVAPTAN

Usual adult dose:

- LUPIN-TOLVAPTAN is to be taken twice a day in two different doses. There are three possible dose combinations that your doctor may prescribe:
  - 45 + 15 mg, for a total daily dose of 60 mg, or
  - 60 + 30 mg, for a total daily dose of 90 mg, or
  - 90 + 30 mg, for a total daily dose of 120 mg.
- Take one tablet of the higher dose (45 mg, 60 mg or 90 mg) in the morning.
- 8 hours later, take one tablet of the lower dose (15 mg or 30 mg).
- This schedule was designed to give you the best balance between the amount of medicine in your body and possible side effects (especially nighttime urination).
- Do not drink grapefruit juice during treatment with LUPIN-TOLVAPTAN. This could cause you to have too great of a drug effect while taking LUPIN-TOLVAPTAN.

Total daily dose (Your doctor will decide which dose is right for you.)	**AM dose** (first thing in the morning)	**PM dose** (8 hours after your AM dose)
60 mg	45 mg	15 mg
90 mg	60 mg	30 mg
120 mg	90 mg	30 mg

Adjusted dose if you are taking certain medicines:

Your doctor will tell you to reduce your usual dose of LUPIN-TOLVAPTAN if you take certain medicines, as these medicines could cause you to have too much LUPIN-TOLVAPTAN in your blood. Your doctor may reduce your dose to the following:

- 30 + 15 mg, for a total daily dose of 45 mg.

Missed dose:

Do not miss or skip doses of LUPIN-TOLVAPTAN. If you miss a dose, take your next dose at the scheduled time and prescribed level. Do not take 2 doses at the same time.

Possible side effects and the importance of adherence

Possible side effects during treatment with LUPIN-TOLVAPTAN and what to do about them:

Known side effects

The expected side effects of LUPIN-TOLVAPTAN treatment are thirst, urinating large amounts and/or frequently, urinating at night, headache, constipation, diarrhea, dry mouth, indigestion, decreased appetite, fatigue, weakness, dizziness, trouble sleeping, muscle spasms, rash, itching and abdominal pain.

When to talk to your healthcare team

Talk with your doctor, nurse or pharmacist if you experience any of the following:

- **Increased levels of potassium in the blood:** symptoms such as irregular heartbeats, muscle weakness and generally feeling unwell
- **Increased levels of uric acid in the blood/gout:** symptoms such as joint pain, commonly in the big toe, followed by redness, swelling or warmth
- **Liver disorder:** symptoms such as yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting or loss of appetite

You should also talk to your healthcare team if you experience a side effect that distresses you.

<u>Stop taking LUPIN-TOLVAPTAN and call your doctor or pharmacist immediately if you experience any of the following:</u>

- **Dehydration:** symptoms such as increased thirst, dry mouth and/or skin, fatigue, decreased amount of urine, headache, dizziness or irregular heartbeats
- **Angioedema and severe allergic reactions:** symptoms such as swelling of the face, eyes, or tongue, difficulty swallowing, wheezing, hives and generalized itching, rash, fever, abdominal cramps, chest discomfort or tightness, difficulty breathing or unconsciousness

Water intake and elimination (urination)

Water intake

As an ADPKD patient, you already know that it is important to drink plenty of water every day. This is also extremely important when you are on LUPIN-TOLVAPTAN.

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

- drink plenty of water throughout the day
- but **do not** drink grapefruit juice
- drink 1–2 glasses of water before bedtime, even if you are not thirsty

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

Water elimination (urination)

As discussed above, people on LUPIN-TOLVAPTAN are likely to experience thirst, urinating large amounts and/or frequently, and urinating at night. This is related to how the medication works. Work with your healthcare team to find ways that you can adapt to these effects, if you have them.

Adhering to LUPIN-TOLVAPTAN treatment

You should not stop taking LUPIN-TOLVAPTAN without talking to your doctor first. If the effects of thirst and/or urination are making it difficult for you to stay on treatment, talk to your healthcare team for help with adapting your daily routine.

PATIENT WALLET CARD

LUPIN GENESIS
PATIENT SUPPORT PROGRAM

1-866-488-6017
support@genesispsp.com



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LUPIN
PHARMA CANADA

Keep this card with you at all times in case of emergency or even for a quick inquiry.

Prescriber's name: _____

Phone number: _____

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