

Taking Tolvaptan

The leaflet aims to answer your questions about taking Tolvaptan to treat your Autosomal Dominant Polycystic Kidney Disease. If you have any questions or concerns, please speak to a doctor or nurse caring for you.

What is Tolvaptan?

Tolvaptan is a medicine that can be used to treat Autosomal Dominant Polycystic Kidney Disease (ADPKD). ADPKD is a genetic condition which causes cysts to develop in your kidneys. For some people, this can cause pain and a worsening of your kidney function.

Normally your body releases a hormone called vasopressin which tells your kidneys to hold on to water. Unfortunately, in people with ADPKD this encourages cyst development. Tolvaptan works by blocking the effect of vasopressin on the kidney, causing your kidneys to release water by producing large amounts of dilute urine. High-quality clinical trials have shown that Tolvaptan can slow the worsening of kidney function and reduce the kidney pain associated with ADPKD.^{1,2} Alternatively, keeping yourself hydrated to maintain a clear (colourless) urine is also believed to be helpful as this reduces the release of vasopressin by the body.

By slowing the decline in kidney function associated with ADPKD, Tolvaptan can delay the need for dialysis or a kidney transplant. The earlier you start and the longer you take Tolvaptan, the greater the benefit will be.

If you start Tolvaptan when your kidney function is slightly below normal (eGFR 85-89) this will delay the need for dialysis or a kidney transplant by ~7.3 years.¹ If you start Tolvaptan when you have half of your normal kidney function (eGFR 45) this will delay the need for dialysis or a kidney transplant by ~2.9 years.¹ If you start Tolvaptan when you have a third of your normal kidney function (eGFR 30) this will delay the need for dialysis or a kidney transplant by ~1.5 years.¹

Figure 1: An example of one of the available brands of Tolvaptan tablets.



What tests will I have to undergo if I start Tolvaptan?

You will need to have a blood test before starting treatment and then every month for the first 18 months after you start Tolvaptan. After this you will need to have a blood test every three months for as long as you continue taking Tolvaptan. This is because Tolvaptan can cause inflammation of the liver (hepatitis) and upset the control of sodium in the blood. If it does happen, it usually occurs within the first 18 months. It is important we identify this quickly so we can stop the Tolvaptan. Any liver inflammation is usually reversible and should resolve when Tolvaptan is stopped. However, there is a small risk that Tolvaptan can lead to permanent liver damage.

How do I take the medicine?

Tolvaptan comes as a tablet which you must swallow, rather than chew. You will need to take Tolvaptan in split doses twice a day (e.g., 60mg in total: 45mg in the early morning, then 15mg eight hours later). The first dose must be taken at least 30 minutes before breakfast.

The second dose must be taken eight hours after the first and it can be taken with or without food. **Do not drink grapefruit juice at any time while you are taking Tolvaptan.** Your daily dose of Tolvaptan may be slowly increased to 90mg (60mg in morning, followed by 30mg) and then to 120mg (90mg, 30mg) by your doctor / pharmacist, if it is tolerated. There must be at least a one-week interval between dose increases, i.e. you will start the medication at 60mg then at least one week later, this may be increased to 90mg, then at least one week after that, if tolerated, may be increased to 120mg.

What should I do if I forget to take the medicine?

If you have forgotten a tablet, you can take this tablet as soon as you remember on that same day. If you forget to take all your tablets one day, take your normal doses the next day – you should **NEVER** take a double dose as this increases your risk of dehydration.

If you do accidentally take more Tolvaptan than you should, you should drink lots of water and contact your doctor or renal pharmacist or local hospital immediately.

Are there any side effects?

(1) FREQUENT URINATION, THIRST AND DEHYDRATION

Whilst taking Tolvaptan, you will pass more urine more often, as much as up to every hour and you will likely need to pass urine during the night.

Due to this, Tolvaptan increases your risk of dehydration and you may experience thirst, dry mouth and dry eyes. You should routinely drink sufficient water to avoid this dehydration, ideally at least four litres per day. You should drink 1-2 glasses of water before bed every night.

If you experience more than two episodes of diarrhoea or vomiting, you should stop taking Tolvaptan until your symptoms have resolved for at least 24 hours. You should continue to drink

plenty of water. If you are going abroad to a hot country or are taking part in intensive exercise, you should discuss this with your doctor or pharmacist and may need to take a holiday from your Tolvaptan to prevent you getting dangerously dehydrated.

(2) LIVER INFLAMMATION

As mentioned above, Tolvaptan can lead to inflammation of the liver, which is why the regular blood tests are very important. This affects up to 1 in 10 people who take the medication. Symptoms of liver damage include nausea, vomiting, abdominal pain, dark urine, yellowing of skin / eyes (jaundice), itchy skin, reduced appetite. If you experience any of the above symptoms, contact your doctor immediately. Most of the time, this liver damage is reversible once treatment with Tolvaptan is stopped.

(3) OTHER SIDE EFFECTS

Other **very common side effects** that may affect **more than 1 in 10 people** include headache, dizziness, and diarrhoea. **Other common side effects** that may affect **up to 1 in 10 people** include muscle cramps, difficulty sleeping, general weakness, weight gain or weight loss.

Is there anything else I need to know?

PREGNANCY AND BREASTFEEDING

Tolvaptan must not be taken if you are trying to get pregnant or are pregnant, as it can harm an unborn baby. It also must not be taken whilst breastfeeding. Reliable contraception must be used whilst taking Tolvaptan and for at least four weeks after stopping, to avoid any chance of pregnancy.

STORAGE

The tablets should be stored in their original container at room temperature, out of reach and sight of children.

How do I get a repeat prescription?

Tolvaptan will be prescribed by your ADPKD clinic (not your GP) so please inform them when you are running low. Wherever possible it will be supplied via home delivery.

Useful sources of information

This leaflet should be read alongside the manufacturer's information leaflet provided with your medication.

The Polycystic Kidney Disease Charity website (<https://pkdcharity.org.uk/>) contains lots of useful information on ADPKD and its treatment, as well as details of upcoming educational events, support groups, a PKD app and a confidential helpline **0300 111 1234** open 9:30am to 5:00pm, Monday to Friday, except bank holidays.

The St George's Kidney Patients' Association website [St George's Kidney Patients Association \(sgkpa.org.uk\)](http://sgkpa.org.uk) contains a lot of useful information for patients with kidney disease in general. It also contains information on upcoming events at St George's and how to get involved locally.

Contact us

If you have any questions or concerns about Tolvaptan, please contact the kidney unit on 020 8725 2705 (Monday to Friday, 9am to 5pm). Out of hours, please contact Champneys ward on 020 8725 0062.

For repeat Tolvaptan prescription requests please contact Pearl Chemist Homecare on 020 8049 6655 or 0800 099 6005 / 6153 (Freephone).

Email: homecare@pearlchemistgroup.co.uk.

The opening hours of Pearl Chemist are 8am to 6pm Monday to Friday, 8am to 12 noon on Saturday and closed on Sundays and Bank Holidays. If you need to contact Pearl Chemist outside of these opening hours regarding an urgent query that cannot wait until the next working day, please call their emergency line on 020 8159 3199.

For more information leaflets on conditions, procedures, treatments and services offered at our hospitals, please visit www.stgeorges.nhs.uk

Additional services

Patient Advice and Liaison Service (PALS)

PALS can offer you advice and information when you have comments or concerns about our services or care. You can contact the PALS team on the advisory telephone line Monday, Tuesday, Thursday and Friday from 2pm to 5pm.

A Walk-in service is available:
Monday, Tuesday and Thursday between 10am and 4pm
Friday between 10am and 2pm.

Please contact PALS in advance to check if there are any changes to opening times.

The Walk-in and Advisory telephone services are closed on Wednesdays.

PALS is based within the hospital in the ground floor main corridor between Grosvenor and Lanesborough Wing.

Tel: 020 8725 2453 **Email:** pals@stgeorges.nhs.uk

NHS Choices

NHS Choices provides online information and guidance on all aspects of health and healthcare, to help you make decisions about your health.

Web: www.nhs.uk

NHS 111

You can call 111 when you need medical help fast but it's not a 999 emergency. NHS 111 is available 24 hours a day, 365 days a year. Calls are free from landlines and mobile phones.

Tel: 111

References

1. Casteleijn, N. F. *et al.* Tolvaptan and Kidney Pain in Patients with Autosomal Dominant Polycystic Kidney Disease: Secondary Analysis from a Randomized Controlled Trial. *Am J Kidney Dis* **69**, 210–219 (2017).
2. Müller, R.-U. *et al.* An update on the use of Tolvaptan for autosomal dominant polycystic kidney disease: consensus statement on behalf of the ERA Working Group on Inherited Kidney Disorders, the European Rare Kidney Disease Reference Network and Polycystic Kidney Disease International. *Nephrology Dialysis Transplantation* **37**, 825–839 (2022).



Reference: REN_TOL_01 **Published:** December 2023 **Review date:** December 2025