Tolvaptan Teva

Patient/Carer Education Brochure

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Contents

What is the purpose of this brochure?

Teva UK provides this patient education brochure for patients with autosomal dominant polycystic kidney disease (ADPKD) who are being treated with Tolvaptan Teva.

This brochure will:

- explain what tolvaptan is, what medical condition it is used for and how it should be used
- provide important safety information
- help you to understand potential side effects of tolvaptan and what to do if they occur

This brochure provides some important information about tolvaptan.

Please read the patient information leaflet found in the medicine package for more details and consult your doctor if you have any questions about your treatment with tolvaptan.

What is tolvaptan?

You have been prescribed tolvaptan because you have "autosomal dominant polycystic kidney disease" or "ADPKD".

This disease causes growth of fluid-filled cysts in the kidneys, which put pressure on surrounding tissues and reduce kidney function, possibly leading to kidney failure.

Tolvaptan is used to treat ADPKD in adults with chronic kidney disease (CKD) stages 1 to 4 with evidence of rapidly progressing disease.

Tolvaptan blocks the effect of vasopressin. Vasopressin is a hormone, which regulates water absorption from the kidneys and is involved in the formation of cysts in the kidneys of ADPKD patients. By blocking the effect of vasopressin, tolvaptan increases urine production and slows the development of kidney cysts in patients with ADPKD. It also helps reduce the symptoms of the disease.

Which patients are not eligible for treatment with tolvaptan?

You should not take tolvaptan if any of the following apply to you:

- you are allergic to tolvaptan or any of the other ingredients of this medication including lactose or benzazepine derivatives (e.g. benazepril, conivaptan, fenoldopam mesylate or mirtazapine)
- you have been told that you have raised levels of liver enzymes in your blood which do not allow treatment with tolvaptan
- you have a condition which is associated with a very low blood volume (e.g. severe dehydration or bleeding)
- you have a condition that increases the sodium in your blood
- your kidneys do not produce urine
- you have difficulty realising when you are thirsty or are unable to drink water

- you are pregnant or breastfeeding (or planning to get pregnant)
- you are unable or unwilling to comply with monthly liver function testing

Which patients should take special care when taking tolvaptan?

You should be careful while taking tolvaptan and tell your doctor if any of the following apply to you:

- you suffer from liver disease
- you cannot drink enough water, you have to limit your fluid intake or you are at an increased risk of water loss
- you have an enlarged prostate or have difficulty urinating
- you suffer from too high or too low blood sodium
- you have diabetes
- you have high levels of uric acid in your blood (which may have caused gout)
- you have galactose intolerance, Lapp lactase deficiency or glucose- galactose malabsorption

Please ask your doctor if you are not sure if any of these apply to you.

How should I take tolvaptan?

You should always take tolvaptan exactly as your doctor has told you. Please check with your doctor or pharmacist if you are not sure.

Tolvaptan needs to be taken in two split doses every day. For the treatment of ADPKD, the total daily dose is usually between 60 mg and 120 mg. Your doctor will start treatment with tolvaptan at 60 mg a day, in split doses of 45 mg and 15 mg. The higher dose is taken upon waking and the lower dose should be taken 8 hours later. Your doctor might increase the dose to 90 mg (60 mg and 30 mg) and then to 120 mg (90 mg and 30 mg) over the following weeks.

If you are taking medication, which belongs to a group called 'CYP3A inhibitors', your doctor might prescribe a lower daily dose of your combined tolvaptan. This is because if used at the same time they may increase your chances of experiencing side effects. Examples of these kinds of medications include some kinds of antibiotics (e.g. clarithromycin, ciprofloxacin, and erythromycin). Consult the patient information leaflet for more details.

Other types of medicines called 'CYP3A inducers' could make tolvaptan less effective and therefore should be avoided. These include medicines used for epilepsy (e.g. carbamazepine, phenytoin), and St John's Wort (a herbal therapy). Other tablets could also be affected by tolvaptan use. It is important to tell your doctor if you are taking any medicines or herbal treatments or supplements of any sort.

You should swallow the tablets whole with a glass of water and should not chew them. The morning dose is to be taken at least 30 minutes before the morning meal. The second daily dose can be taken with or without food. Do not drink grapefruit juice at any time while you are taking tolvaptan.

It is important to drink plenty of fluids when taking tolvaptan

Tolvaptan will make you pass urine more often than before and this may make you more thirsty than usual.

You should drink plenty of water or other watery drinks whether or not you feel thirsty in order to avoid excessive thirst or dehydration. Please note that you should not drink grapefruit juice while you are taking tolvaptan. You should drink 1–2 glasses of fluid before bedtime and drink more if you pass urine during the night time. Special care must be taken if you have any condition that could increase your chances of becoming dehydrated, for example, if you are vomiting or have diarrhoea. In these situations, you should drink more fluids.

Symptoms of dehydration may include:

- increased thirst
- dark yellow and strong-smelling urine
- feeling dizzy or lightheaded
- feeling tired
- decreased urination
- dry mouth, lips, eyes or skin

You should inform your doctor immediately, and seek medical advice, if you experience any of these signs and symptoms. If dehydration is left untreated, it can become severe.

Severe dehydration is a medical emergency and requires immediate medical attention. Symptoms can include unusual tiredness, weak/rapid pulse, confusion, dizziness, not urinated all day and fits (seizures).

If you experience any of these symptoms, contact your doctor/ call 999/go to A&E immediately to seek medical advice.[1]

If you forget to take tolvaptan

If you forget to take your medicine, you should take the dose as soon as you remember on the same day.

If you forget to take the medicine completely one day, you should just take your normal dose on the following day.

You should not take a double dose to make up for forgetting to take individual doses.

1. NHS dehydration – available at https://www.nhs.uk/conditions/Dehydration/

If you accidentally take more tolvaptan than prescribed

If you have taken more tablets than your prescribed dose, drink plenty of water and contact your doctor or treatment centre immediately.

Remember to take the medicine with you so that it is clear what you have taken.

Do not take any more tolvaptan tablets until you have spoken to the doctor at your treatment centre.

What important side effects of tolvaptan should I be aware of?

Tolvaptan may cause your liver not to work properly and increase the level of liver enzymes and bilirubin in your blood.

To check for any changes in your liver function, your doctor will conduct blood tests:

- before starting treatment with tolvaptan
- every month for the first 18 months of treatment
- every 3 months thereafter

The following signs indicate that you may have potential liver problems:

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

Tolvaptan causes water loss because it increases your urine production. This water loss may result in side effects such as dry mouth and thirst or even more severe side effects like kidney problems. If you have a condition that reduces the amount of fluid, you can take in, or if you are at an increased risk of losing water, then you are at an increased risk of becoming dehydrated. This may happen, for example, if you are vomiting or have diarrhoea.

What should I do if I experience any of these signs?

You should inform your doctor immediately if you experience any of the signs mentioned above and seek advice from your doctor.

You may need to get additional blood testing.

Treatment with tolvaptan will be stopped and may be restarted if the blood tests for liver function are normal.

Is it safe to take tolvaptan while trying to become pregnant, during pregnancy or while breastfeeding?

You should not take tolvaptan if you are trying to become pregnant or during pregnancy, as it may result in side effects to you and developmental abnormalities in your unborn baby.

Women of childbearing potential must use one effective method of pregnancy prevention for at least 4 weeks before starting therapy, during therapy – even in the case of dose interruptions – and for at least a further 4 weeks after stopping tolvaptan.

You should discuss with your physician the most suitable form of contraception to use.

This is because the use of some contraceptives containing oestrogen may increase the growth and development of cysts in the liver.

You should not breastfeed while taking tolvaptan and for one month after stopping tolvaptan.

What should I do if I become pregnant or think I may be pregnant while taking tolvaptan or within 30 days after stopping tolvaptan?

You should stop taking tolvaptan immediately and inform your prescribing doctor immediately so your pregnancy can be monitored.

What is the tolvaptan patient alert card and how should I use it?

When you are first prescribed tolvaptan you will be given the tolvaptan patient alert card by your doctor or nurse.

This card contains important safety information regarding the risks of liver injury and dehydration while taking tolvaptan and what to do should signs or symptoms occur. It also contains the emergency contact details of your doctor or treatment centre. The contact details will be added to the card by your healthcare provider.

You should keep it with you in your wallet or bag at all times in case of emergency.

If you have not received the patient alert card please contact your doctor or nurse.

Reporting side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

Side effects can also be reported to Teva UK Limited on 0207 540 7117 or medinfo@tevauk.com.

By reporting side effects, you can help provide more information on the safety of this medicine.

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