Prokitav® (tolvaptan)

Patient/carer Education Guide

Prokitav 45 mg and 15 mg Tablets
Prokitav 60 mg and 30 mg Tablets
Prokitav 90 mg and 30 mg Tablets

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA.

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Content

What is the purpose of this brochure?

This patient education brochure is provided for patients with hyponatremia or autosomal dominant polycystic kidney disease (ADPKD) who are being treated with Prokitav (tolvaptan).

This brochure provides some important information about tolvaptan

This brochure will:

- Explain what tolvaptan is, what medical condition it is used for and how it should be used
- Provide some of the important safety information with respect to the risk that tolvaptan can cause your liver to not work properly, as well as cause excessive water loss and what to do if this occurs
- Inform you on the importance of pregnancy prevention while being treated with tolvaptan

Important: However, for more details, please read the patient information leaflet found in the medicine packaging, which contains the complete information, including other precautions, you need to know when taking tolvaptan.

Consult your doctor, pharmacist or nurse, if you have any questions about your treatment with tolvaptan.

What is Prokitav?

Prokitav is indicated to slow the progression of cyst development and renal insufficiency of autosomal dominant polycystic kidney disease (ADPKD) in adults with chronic kidney disease (CKD) stage 1 to 4 at initiation of treatment with evidence of rapidly progressing disease.

Prokitav contains the active substance tolvaptan which blocks the effect of the hormone vasopressin.

By blocking the effect of vasopressin, tolvaptan slows the development of kidney cysts in patients with ADPKD, and increases urine production.

When not to take tolvaptan?

Your doctor will determine whether it is appropriate for you to receive treatment with tolvaptan. Due to some of the risks associated with tolvaptan therapy, such as potential effects which may cause your liver not to work properly, and the potential to cause dehydration, you should not take tolvaptan if any of the following applies to you:

- 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 difficulty realising when you are thirsty or unable to drink sufficient amounts of water
- You are planning to get pregnant
- You are pregnant
- You are breastfeeding

For a full list of when not to take tolvaptan, please refer to the Prokitav patient information leaflet.

How should I take tolvaptan?

Tolvaptan can only be prescribed by doctors who are specialized in the treatment of hyponatremia and ADPKD.

The morning dose (the higher dose) is to be taken at least 30 minutes before the morning meal. The second daily dose (the lower dose) can be taken with or without food and should be taken 8 hours later.

Other medicines could affect and be affected by tolvaptan use.

It is important to tell your doctor or pharmacist if you are taking, have recently taken, or might take any medicines (including medicines obtained without a prescription).

Consult the patient information leaflet for more details.

Risk of dehydration: 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.

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 or severe dehydration.

It is therefore important that you have access to water and that you are able to drink sufficient amounts when you feel thirsty.

Do not drink grapefruit juice at any time while you are taking tolvaptan.

Talk to your doctor before taking tolvaptan if you cannot drink enough water or if you have to restrict your fluid intake.

If you have a disease or 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.

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 skin1
- Poor skin elasticity

It is important that you contact your doctor if you develop any of the symptoms listed above.

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 immediately to seek medical advice.

Potential for liver injury with tolvaptan treatment

Tolvaptan may cause your liver to not work properly, and increase the level of liver enzymes and bilirubin (a substance that can cause yellowing of skin or eyes) in your blood. 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.

Talk to your doctor before taking tolvaptan if you suffer from liver disease.

Tolvaptan may cause your liver not to work properly. 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

Depending on the results of your liver function tests, treatment with tolvaptan may need to be stopped.

You should not take tolvaptan if you are unable or unwilling to comply with liver function testing.

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

- Tiredness
- Loss of appetite
- Pain in the abdomen
- Dark urine
- Yellowing of the skin or eyes (jaundice)
- Nausea
- Vomiting
- Fever
- Itching of your skin
- Flu-like syndrome (joint and muscle pain with fever)

<u>It is important that you contact your doctor if you develop any of the symptoms listed above.</u>

The importance of pregnancy prevention before and during tolvaptan treatment

Do not take tolvaptan if you are trying to become pregnant, or during pregnancy, as it may affect your unborn baby.

Women of childbearing potential must use reliable contraceptive measures for 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 four weeks after stopping tolvaptan.

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

If you are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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

In case you become pregnant, stop taking tolvaptan and inform your prescribing doctor immediately so that your pregnancy is 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 if certain 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 treating doctor.

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

If you have not received a 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. By reporting side effects, you can help provide more information on the safety of this medicine.

Any suspected adverse reactions to Prokitav should be reported to Jazeera Pharmaceutical Industries at the following email address: SAPV@hikma.com and/or to Saudi Food and Drug Administration (SFDA) at the following contact details:
E-mail: npc.drug@sfda.com,
Website: https://ade.sfda.gov.sa,
Call center number: 19999, or QR Code: