Otsuka

JINARC®(tolvaptan)

Patient educational material

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1. What is the purpose of this Educational Material?

This Patient Educational Material is provided by Otsuka Pharmaceuticals (U.K.) Ltd. for patients with autosomal dominant polycystic kidney disease (ADPKD) who are receiving treatment with tolvaptan.

This material 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 on the risks of liver injury and excessive water loss and what to do if they occur. Inform you on the importance of pregnancy prevention before, during and after treatment with tolvaptan

Important: Please read the 'Package leaflet: Information for the patient' (found in the medicine package) which contains the complete information, including other precautions, you need to know when taking tolvaptan. Talk to your doctor if you have any questions about your treatment with tolvaptan.

2. What is tolvaptan?

You have been prescribed tolvaptan because you have 'autosomal dominant polycystic kidney disease' or 'ADPKD'. 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 the hormone vasopressin. By blocking the effect of vasopressin, tolvaptan increases urine production and slows the growth of kidney cysts in patients with ADPKD.

3. Which patients are not eligible for treatment with 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 apply to you:

- If you have been told that you have raised levels of liver enzymes in your blood which do not allow treatment with tolvaptan
- If you are unable or unwilling to comply with monthly blood test for checking liver function
- If you have any condition which is associated with a very low blood volume
- If you have difficulty realising when you are thirsty or are unable to drink sufficient amounts of water

Avoid treatment with tolvaptan if you are a woman of childbearing potential, and you are planning to get pregnant, are pregnant, or breastfeeding.

4. Which patients should take special care when taking tolvaptan?

You should **take care** while taking tolvaptan and tell your doctor:

- If you suffer from liver disease, or other medical conditions or illness
- If you cannot drink enough water or if you have to limit your fluid intake or you are at an increased risk of water loss
- If you are not sure that tolvaptan therapy may be appropriate for you

5. What are some of the important side effects of tolvaptan that I should be aware of?

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

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 symptoms 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
- Itching
- Flu-like syndrome (joint and muscle pain)
- Fever

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

6. Is it important to drink plenty of fluids when taking tolvaptan?

Tolvaptan also 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.

Symptoms of dehydration may include:

- Increased thirst
- Dry mouth
- Feeling tired or sleepy
- Decreased urination
- Headache
- Dry skin
- Dizziness
- Rapid heart rate
- Confusion
- Poor skin elasticity

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

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. Before bedtime you should drink 1 or 2 glasses of fluid and drink more if you pass urine during the night time. Special care must be taken if you have a disease that increase the risk of water loss, e.g. in case of vomiting or diarrhoea.

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

You must 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 effective and reliable method of contraception at least four weeks before therapy is initiated, during therapy and even in the case of dose interruptions, and for at least a further four weeks after stopping tolvaptan. In case you become pregnant, stop taking tolvaptan and inform your prescribing doctor immediately so that your pregnancy can be monitored.

You must not breastfeed while taking tolvaptan.

8. What is the tolvaptan Patient Card and how should I use it?

When you are first prescribed tolvaptan you will be given the tolvaptan Patient 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 Card please contact your doctor or nurse.

9. How should I report side effects with tolvaptan?

If you get any of the side effects mentioned, talk to your doctor, pharmacist or nurse as soon as possible. You can also speak to them about any other side effects, including those not listed in the package leaflet. You can also report side effects directly to HPRA Pharmacovigilance at **www.hpra.ie**,

Adverse events can also be reported to Otsuka at **opuksafety@otsuka.co.uk** or by calling **+353 1 695 0725**. For further information, please contact Otsuka Medical Information at **medical.information@otsuka-europe.com** or call **+353 1 695 0725**.

This patient educational material fulfils the conditions of the marketing authorisation and has been approved by the HPRA
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