Jinarc®▼

(tolvaptan)

Patient Education Brochure

Contents

1. What is the purpose of this brochure?

This Patient Education Brochure is provided by Otsuka Pharmaceutical Europe LTD. for patients with autosomal dominant polycystic kidney disease (ADPKD) who are receiving treatment with Jinarc® (tolvaptan).

This brochure will:

- Explain what Jinarc® 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 Jinarc can cause your liver to not work properly ®, as well as cause excessive water loss, and what to do if they occur.
- Inform you on the importance of pregnancy prevention while being treated with Jinarc.

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 Jinarc. Talk to your doctor if you have any questions about your treatment with Jinarc®.

2. What is Jinarc®?

You have been prescribed Jinarc® because you have "autosomal dominant polycystic kidney disease" or "ADPKD". Jinarc is used to treat ADPKD in adults with chronic kidney disease (CKD) stages 1 to 4 with evidence of rapidly progressing disease.

Jinarc contains the active substance tolvaptan which blocks the effect of the hormone vasopressin. By blocking the effect of vasopressin, Jinarc increases urine production and slows the growth of kidney cysts in patients with ADPKD.

3. Which patients are not eligible for treatment with Jinarc®?

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

- If you have been told that you have raised levels of liver enzymes in your blood which do not allow treatment with Jinarc®

- 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 Jinarc if you are a female, and you are planning to get pregnant, are pregnant, or breastfeeding.

4. Which patients should take special care when taking Jinarc®?

You should take care while taking Jinarc® 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 Jinarc therapy may be appropriate for you

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

Jinarc® 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 Jinarc® 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 Jinarc®
- 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 Jinarc®?

Jinarc 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.

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.

Jinarc® 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. 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 diseases that increase the risk of water loss, e.g. in case of vomiting or diarrhoea.

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

You must not take Jinarc® 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 pregnancy prevention 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 Jinarc®. You must not breastfeed while taking Jinarc®. In case you become pregnant, stop taking Jinarc® and inform your prescribing doctor immediately so that your pregnancy can be monitored.

8. What is the Jinarc® Patient Alert Card and how should I use it?

When you are first prescribed Jinarc® you will be given the Jinarc® Patient Alert Card by your doctor or nurse. This card contains important safety information regarding the risks of liver injury and dehydration while taking Jinarc® 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.

9. How should I report adverse drug reactions with Jinarc®?

Please report all suspected adverse drug reactions to Otsuka Pharmaceutical Europe LTD local representative Swixx Biopharma S.M.S.A Pharmacovigilance Department on +30 214 444 9670 (including out of hours), email medinfo.malta@swixxbiopharma.com and to the Medicines Authority ADR reporting form, which is available online at www.medicinesauthority.gov.mt/adrportal , and sent by post or email to:

P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000

E: postlicensing.medicinesauthority@gov.mt