Otsuka

JINARC®▼ (tolvaptan)

Patient/carer education brochure

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See www.mhra.gov.uk/yellowcard for how to report side effects.

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What is the purpose of this brochure?

This patient education brochure is provided by Otsuka Pharmaceuticals (U.K.) Ltd for patients with autosomal dominant polycystic kidney disease (ADPKD) who are being treated with Jinarc (tolvaptan).

This brochure provides some important information about Jinarc.

This brochure will:

- Explain what Jinarc 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 Jinarc and what to do if they occur

However, for more details, please read the patient information leaflet found in the medicine packaging, which contains the complete information you need to know when taking Jinarc.

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

What is Jinarc?

You have been prescribed Jinarc 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. 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 vasopressin, a hormone involved in the formation of cysts in the kidneys of ADPKD patients.

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

When not to take Jinarc?

Do not take Jinarc if any of the following applies to you:

- You are allergic to tolvaptan, or any of the other ingredients of this medicine (lactose monohydrate, maize starch, microcrystalline cellulose, hydroxypropylcellulose, magnesium stearate, indigo carmine aluminium lake), or benzazepine 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 Jinarc
- 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
- You are pregnant
- You are breastfeeding

How should I take Jinarc?

Jinarc can only be prescribed by doctors who are specialised in the treatment of ADPKD.

Always take Jinarc exactly as your doctor has told you. Please check with your doctor or pharmacist if you are not sure.

Jinarc 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 normally start treatment with Jinarc at 60 mg a day, in split doses of 45 mg and 15 mg. The higher dose (45 mg) is taken upon waking and the lower dose (15 mg) should be taken 8 hours later.

Your doctor may gradually increase the total daily dose to 90 mg (split doses of 60 mg and 30 mg) and then to a total daily dose of 120 mg (split doses of 90 mg and 30 mg), over the following weeks.

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, 8 hours later.

Swallow the tablets without chewing, with a glass of water. Do not drink grapefruit juice at any time while you are taking Jinarc.

Other medicines could affect and be affected by Jinarc 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 Jinarc

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

Jinarc 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.

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

Before bedtime you must drink 1 or 2 glasses of water, even if you do not feel thirsty, and you must also drink water after you urinate at night.

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

Talk to your doctor before taking Jinarc 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.

This may happen, for example, if you are vomiting or have diarrhoea; special care must be taken in these situations and 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[1]

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]

1 NHS dehydration – available at https://www.nhs.uk/conditions/Dehydration/ (last accessed Oct 2020).

Potential for liver injury with Jinarc treatment

Jinarc 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.

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

Jinarc 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 Jinarc
- Every month for the first 18 months of treatment
- Every 3 months thereafter

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

You should not take Jinarc 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)

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

The importance of pregnancy prevention before and during Jinarc treatment

Do not take Jinarc 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 4 weeks after stopping Jinarc.

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.

Do not breastfeed while taking Jinarc and for one month after stopping Jinarc.

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

You should stop taking Jinarc at once and inform your prescribing doctor immediately so that your pregnancy can be monitored.

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 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. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects, you can help provide more information on the safety of this medicine.

Adverse events can also be reported to Otsuka at **opuksafety@otsuka.co.uk** or by calling **0808 168 6726**.

For further information, please contact Otsuka Medical Information at **medical.information@otsuka-europe.com** or call **0203 747 5300**.

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