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 to HPRA Pharmacovigilance at www.hpra.ie, via Email at medsafety@hpra.ie or via phone: +353 1 676 4971.

Adverse events can also be reported to Otsuka at opuksafety@otsuka.co.uk or by calling +353 1 695 0725.

Contents

What is the purpose of this brochure?

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

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.

This brochure provides some important information about JINARC.

For more information please read the patient information leaflet which can be found in the medicine package or online on the HPRA website.

Please consult your doctor 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 should I not take JINARC?

- if you are allergic to tolvaptan or any of the other ingredients of this medication (lactose, maize starch, microcrystalline cellulose, hydroxypropylcellulose, magnesium stearate and indigo carmine aluminium lake) or if you are allergic to benzazepine or benzazepine derivatives (e.g. benazepril, conivaptan, fenoldopam mesylate or mirtazapine)
- 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 have a condition which is associated with a very low blood volume
- if your kidneys do not produce urine
- if you have a condition that increases the sodium in your blood
- if you have difficulty recognising when you are thirsty
- if you are pregnant or breastfeeding.

How should I take JINARC?

JINARC can only be prescribed by doctors who are specialised in the treatment of ADPKD. You should 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 different 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 JINARC 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.

Consult the patient information leaflet for more details.

Other tablets could be affected by JINARC 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 JINARC.

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.

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 JINARC. You should drink 1–2 glasses of fluid before bedtime and drink more if you pass urine during the night time.

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.

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 diarrhea; special care must be taken in these situations and you should drink more fluids.

Symptoms of dehydration may include:

- increased thirst
- dry mouth
- feeling tired or sleepy
- decreased urination
- headache
- dry skin and poor elasticity
- rapid heart rate
- dizziness
- confusion.

You should inform your doctor immediately if you experience any of these signs and seek medical advice.

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

JINARC may cause your liver not to work properly

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

- before starting treatment with JINARC
- every month for the first 18 months of treatment
- every three months thereafter.

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

Please inform your doctor immediately if you have signs that could indicate potential liver problems such as:

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

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

You should 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 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 JINARC.

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

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 immediately 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 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.

What should I do if I experience any side effects?

If you get any of the mentioned side effects, 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, via Email at medsafety@hpra.ie or via phone: +353 1 676 4971.

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 medicine is subject to additional monitoring. This will allow quick identification of new safety information.

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

Otsuka

IE-JIN-2000010 September 2020