

PATIENT Alert Card

Safety information for patients
prescribed JINARC ▼ (tolvaptan)

Please keep this card with
you at all times



Patient's name

Date Jinarc first prescribed

Doctor's name

Treatment centre's name

Treatment centre's contact number

Reporting of side effects

If you get any of the side effects listed in the package leaflet, 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**.

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

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

Important safety information for patients and carers

JINARC[®] ▼ can cause liver injury

JINARC may cause your liver not to work properly. Consult your doctor immediately if you experience any of these **symptoms that could indicate potential liver problems** (*please see next page*):

- 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)

JINARC[®] ▼ can cause severe dehydration

JINARC blocks the action of vasopressin (a hormone involved in the formation of cysts in the kidneys of ADPKD patients). This results in an increase in urination which may lead to severe dehydration or excessive water loss.

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

Drink plenty of fluids to avoid dehydration or excessive water loss and consult your doctor if you are not able to drink fluids by mouth. 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 urinating at night.

Special care must be taken if you have a disease that reduces appropriate fluid intake or if you are at increased risk of water loss e.g. vomiting/diarrhoea. Seek medical advice immediately if you experience any of these signs and suspect you are becoming dehydrated.

▼ 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 HPRC Pharmacovigilance at www.hpra.ie, via Email at medsafety@hpra.ie or via phone: **+353 1 676 4971**. For further information, please contact Otsuka Medical Information at medical.information@otsuka-europe.com or call **+353 1 695 0725**.

