PATIENT Card

Safety information for patients prescribed JINARC (tolvaptan)

Please keep this card with you at all times

Otsuka

Patient's name

Date tolvaptan 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**,
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

Tolvaptan can affect how your liver works

Consult your doctor if you experience symptoms of

- Tiredness
- Itching
- Fever
- Nausea
- Vomiting
- Loss of appetite
- Dark urine or
- Yellowing of skin or eyes
- Joint and muscle pain with fever (flu-like syndrome)
- Upper abdominal pain or discomfort

Tolvaptan can cause severe dehydration.

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.

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

Important safety information for emergency carers

Tolvaptan may cause liver injury. Blood tests for liver function must be performed periodically (monthly for the first 18 months, then every 3 months of continuing treatment). Therapy should be stopped or discontinued if significant increase of liver enzymes and/or clinical symptoms of hepatic injury persist.

Tolvaptan can produce significant 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
- dizziness
- rapid heart rate
- confusion
- poor skin elasticity.

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