Patient Card

This Patient Card is meant for patients currently being treated with JINARC®▼tolvaptan.

Please keep this card with you at all times while you are on treatment with tolvaptan and for one week post-treatment.

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Otsuka

Patient Card

Present this card to any healthcare professional that you see, before any medical treatment or intervention.

Patient’s name

Date tolvaptan first prescribed

Doctor’s name

Treatment centre’s name

Treatment centre’s contact number

Reporting of side effects

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

Please report suspected side effects to the MHRA through the Yellow Card scheme. You can report via: the Yellow Card website **www.mhra.gov.uk/yellowcard** or the free Yellow Card app available from the **Apple App Store** or **Google Play Store**.

Alternatively you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

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

Important safety information for patients

Tolvaptan can cause your liver not to work properly.

Your doctor will arrange blood tests for liver function testing:

- Before starting treatment with tolvaptan
- Monthly for the first 18 months of treatment
- Then every 3 months thereafter

Inform your doctor immediately if you experience any of these signs that could indicate potential liver problems:

- 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)

Tolvaptan can cause dehydration / severe dehydration.

Tolvaptan can increase your urine production which may result in excessive water loss and dehydration.

Drink plenty of fluids to avoid dehydration and consult your doctor if you are unable to drink or if you experience any of the following symptoms.

Symptoms of dehydration may include:

- Increased thirst
- Dry mouth
- Feeling tired or sleepy
- Sunken eyes
- Decreased urination
- Dark yellow, strong smelling urine
- Dizziness

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, confusion, dizziness, not urinated all day.

If you experience any of these symptoms, contact your doctor, call 111 or go to A&E immediately to seek medical advice.[1]

1 NHS dehydration – available at https://www.nhs.uk/conditions/Dehydration/ (last accessed May 2024).

Important safety information for HCPs

Tolvaptan blocks the action of vasopressin in the kidney.

This can result 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, dizziness, rapid heart rate, confusion and poor skin elasticity.

Tolvaptan can cause liver injury.

Blood tests for liver function testing must be performed periodically (monthly for the first 18 months, then every 3 months thereafter).

Therapy should be interrupted or discontinued if significant increase of liver enzymes and/or clinical symptoms of liver injury persist.

For more information please contact Otsuka Medical Information at **medical.information@otsuka-europe.com** or call **0808 168 6726.**

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