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

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

# Patient Card

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

**Patient's name**

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version number: 01
MHRA approval date: May 2025

**Date tolvaptan first prescribed**

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**Doctor's name**

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**Treatment centre's name**

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**Treatment centre's contact number**

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## Reporting of 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.

Please report suspected side effects to the MHRA through yellow card scheme. You can report via: the Yellow Card website www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App 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 Zentiva Medical Information by online form (https://www.zentiva.co.uk/contact/mi-form), by email (UKMedInfo@zentiva.com) or by telephone (0800 090 2408)

## 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
- Nausea
- Loss of appetite
- Vomiting
- Pain in the abdomen
- Fever
- Dark urine
- Itching of your skin
- Yellowing of skin or eyes (jaundice)
- 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 • Decreased urination • Dry mouth • Dark yellow, strong smelling urine • Feeling tired or sleepy • Dizziness • Sunken eyes

**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 or go to A&E immediately to seek medical advice[1].

[1] NHS dehydration – available at https://www.nhs.uk/conditions/Dehydration/ (last accessed Apr 2025).

## 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 Zentiva Medical Information by online form (https://www.zentiva.co.uk/contact/mi-form), or by telephone (0800 0902408).