Front

Symptoms of dehydration may include:

- Increased thirst
- Feeling tired or sleepy
- Decreased urination
- Dizziness

Dry mouth

- Sunken eyes
- Dark yellow, strong smelling

11If 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.

1NHS dehydration - available at https://www.nhs.uk/conditions/Dehydration/ (last accessed Jun 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 Ifor 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.

¹For more information, please contact Dr. Reddys's Medical Information at drreddysgb@eu.propharmagroup.com or by calling + 44 (0) 1748 828873 Version 1.0 Date of approval: 24.0ct.2025

Patient Card

Dr.Reddy's

This Patient Card is meant for patients currently being treated with Ttolvaptan.

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

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

Patient's name

Date tolvaptan first prescribed.

Version 1.0 Date of approval: 24.0ct.2025

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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 Ischeme. You can report via: The Yellow Card website

www.mhra.gov.uk/yellowcard or the free Yellow Card app available from Google Play or the Apple 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 Dr. Reddy's at drreddysgb@eu.propharmagroup.com or by calling + 44 (0) 1748 828873.

Important safety information for patients Tolyaptan can cause your liver not to work properly. Your doctor will arrange blood tests for liver I 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 Itching of your skin
- Fever Flu-like syndrome (joint and

muscle pain with fever)

¹Tolvaptan 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.