

## Tolvaptan Patient Card

Patient's Name:

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Date Tolvaptan first prescribed:

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Doctor's Name:

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Hospital name and telephone number:

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### **Important safety information for patients**

#### **Tolvaptan can affect how your liver works.**

Consult your doctor if you experience symptoms of tiredness, loss of appetite, upper abdominal pain or discomfort, fever, dark urine or yellowing of skin or eyes, joint and muscle pain with fever (flu-like syndrome), itching, nausea and vomiting.

#### **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.

### **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 and poor skin elasticity. For more info or for reporting suspected adverse drug reactions to Otsuka Pharmaceutical Europe LTD local representative Swixx Biopharma S.M.S.A. Pharmacovigilance Department on +30 214 444 9670 (24h), email: [medinfo.malta@swixxbiopharma.com](mailto:medinfo.malta@swixxbiopharma.com) and to the Maltese Medicines Authority using the Medicines Authority ADR reporting form, which is available online at <https://medicinesauthority.gov.mt/adrportal>, and sent by post or email to:

P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 E: [postlicensing.medicinesauthority@gov.mt](mailto:postlicensing.medicinesauthority@gov.mt)