

PACKAGE LEAFLET: INFORMATION FOR THE USER

Tolvat 15 mg tablets

Tolvat 30 mg tablets

Tolvaptan

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Tolvat is and what it is used for
2. Before you take Tolvat
3. How to take Tolvat
4. Possible side effects
5. How to store Tolvat
6. Further information

1. WHAT Tolvat IS AND WHAT IT IS USED FOR

Tolvat, which contains the active substance tolvaptan, belongs to a group of medicines called vasopressin antagonists. This means that it prevents vasopressin having its effect on water retention. This leads to a reduction in the amount of water in the body by increasing urine production and as a result it increases the level of sodium in your blood.

You have been prescribed Tolvat because you have a disease called “syndrome of inappropriate antidiuretic hormone secretion” (SIADH). This disease causes an inappropriate production of the hormone vasopressin which has caused the sodium levels in your blood to get too low (hyponatraemia). That can lead to difficulties in concentration and memory, or in keeping your balance.

2. BEFORE YOU TAKE Tolvat

Do not take Tolvat

- if you are allergic to tolvaptan or any of the other ingredients of Tolvat (see section 6)
- if your kidneys do not work (no urine production)
- if you have a condition which increases the salt in your blood (“hypernatraemia”)
- if you have a condition which is associated with a very low blood volume
- if you do not realise when you are thirsty
- if you are pregnant

- if you are breastfeeding.

Take special care with Tolvat

Before taking Tolvat tell your doctor:

- if you cannot drink enough water or if you are fluid restricted
- if you have difficulties in urination or have an enlarged prostate
- if you suffer from liver disease
- if you have diabetes.

Drinking enough water

Tolvat causes water loss because it increases your urine production. This water loss may result in side effects such as dry mouth and thirst or even more severe side effects like kidney problems (see section 4). It is therefore important that you have access to water and that you are able to drink sufficient amounts when you feel thirsty.

Children

Tolvat is not suitable for children and adolescents (under age 18).

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Products containing ketoconazole (against fungal infections), macrolide antibiotics, or diltiazem (treatment for high blood pressure and chest pain) may increase the effects of Tolvat. Tolvat may increase the effect of digoxin (used for treatment of irregularities of heart beat and heart failure). Barbiturates (used to treat epilepsy/seizures and some sleep disorders) or rifampicin (against tuberculosis) may decrease the effects of Tolvat.

Other products which increase the salt in your blood or which contain large amounts of salt may increase the effects of Tolvat. Medicines which also increase your urine production (diuretics) may further increase the risk of water loss related side effects (see “Drinking enough water” above). Therefore, please tell your doctor about all medicines you are receiving or have recently received, including medicines obtained without a prescription.

Tolvat may reduce the effect of desmopressin (used to increase blood clotting factors).

It may still be alright for you to take these medicines and Tolvat together. Your doctor will be able to decide what is suitable for you.

Taking Tolvat with food and drink

- Tolvat tablets can be taken with or without food.
- Avoid drinking grapefruit juice when taking Tolvat.

Pregnancy and breastfeeding

Pregnant women must not take this medicine.

Before taking Tolvat you must tell your doctor if you are pregnant, if you think you are pregnant, or if you intend to become pregnant.

Breastfeeding women must not take this medicine.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Tolvat may occasionally make you feel dizzy or weak or you may faint for a short period.

Important information about some of the ingredients of Tolvat

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE Tolvat

- Treatment with Tolvat will be initiated in hospital
- Always take Tolvat exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- For treatment of your low sodium (hyponatraemia), the dose can be from 15 mg to 60 mg once a day. Your doctor will start with a dose of 15 mg and may then increase it to a maximum of 60 mg to achieve the desired level of serum sodium. To monitor the effects of Tolvat your doctor will do regular blood tests.
- Swallow the tablet without chewing, with a glass of water.
- Take the tablets once a day preferably in the morning with or without food.

If you take more Tolvat than you should

If you have taken more tablets than your prescribed dose, drink plenty of water and contact your doctor or your local hospital immediately. Remember to take the medicine pack with you so that it is clear what you have taken.

If you forget to take Tolvat

If you forget to take your medicine, you should take the dose as soon as you remember on the same day. If you do not take your tablet on one day, take your normal dose on the next day. DO NOT take a double dose to make up for forgotten individual doses.

If you stop taking Tolvat

If you stop taking Tolvat this may lead to reoccurrence of your low sodium. Therefore, you should only stop taking Tolvat if you notice side effects requiring urgent medical attention (see section 4) or if your doctor tells you to.

If you have further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Tolvat can cause side effects, although not everybody gets them.

These side effects may occur with certain frequencies, which are defined as follows:

- very common: affects more than 1 user in 10
- common: affects 1 to 10 users in 100
- uncommon: affects 1 to 10 users in 1,000
- rare: affects 1 to 10 users in 10,000
- very rare: affects less than 1 user in 10,000
- not known: frequency cannot be estimated from the available data.

If you notice any of the following side effects, you may need urgent medical attention. Stop taking Tolvat and immediately contact a doctor or go to the nearest hospital if you:

- find it difficult to urinate
- find a swelling of the face, lips or tongue, itching, generalised rash, or severe wheezing or breathlessness.

Side effects reported in clinical studies with Tolvat were:

Very common

- thirst
- nausea

Common

- raised levels of liver enzymes in the blood
- dry mouth
- excessive drinking of water
- increased need to urinate, or to urinate more frequently
- water loss
- tiredness, general weakness
- decreased appetite
- constipation
- dizziness
- low blood pressure when standing up
- fainting
- patchy bleeding in the skin
- itching
- fever
- high levels of sodium, potassium, creatinine, uric acid and blood sugar
- rapid rise in level of sodium
- decrease in level of blood sugar
- headache
- general feeling of being unwell
- diarrhoea
- blood in urine

Uncommon

- increase of bilirubin in the blood
- kidney problems
- sense of taste altered
- itchy rash

Consult your doctor if symptoms of fatigue, loss of appetite, right upper abdominal discomfort, dark urine or jaundice (yellowing of skin or eyes) occur.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE TOLVAT

Keep out of the reach and sight of children.

Do not use Tolvat after the expiry date which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light and moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Tolvat contains

The active substance is tolvaptan.

Each Tolvat 15 mg tablet contains 15 mg tolvaptan.

Each Tolvat 30 mg tablet contains 30 mg tolvaptan.

The other ingredients are lactose monohydrate, maize starch, microcrystalline cellulose, hydroxypropylcellulose, magnesium stearate, Brilliant Blue Fcf aluminium lake and Polysorbate 80.

What Tolvat looks like and contents of the pack

Tolvat 15 mg is a light blue colored, capsule shaped, biconvex uncoated tablets with plain surface on both sides.

Tolvat 30 mg is a light blue colored, capsule shaped, biconvex uncoated tablets with plain surface on both sides.

10 tablets of Tolvaptan 15 mg are proposed to be marketed in Plain Aluminium blister foil on one side and Printed Aluminium blister foil as base foil on the other side in the form of a Alu-Alu blister pack and such 1 blister pack is further packed in a printed carton along with instructions for use. and

10 tablets of Tolvaptan 30 mg are proposed to be marketed in Plain Aluminium blister foil on one side and Printed Aluminium blister foil as base foil on the other side in the form of a Alu-Alu blister pack and such 1 blister pack is further packed in a printed carton along with instructions for use.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

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