

## MEDICATION GUIDE

### Tolvaptan Tablets (tol-VAP-tan)

Read the Medication Guide that comes with tolvaptan tablets before you take them and each time you get a new prescription. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or your treatment. Share this important information with members of your household.

#### What is the most important information I should know about tolvaptan tablets?

##### 1) Tolvaptan tablets may make the salt (sodium) level in your blood rise too fast.

This can increase your risk of a serious condition called osmotic demyelination syndrome (ODS). ODS can lead to coma or death. ODS can also cause new symptoms such as:

- trouble speaking
- swallowing trouble or feeling like food or liquid gets stuck while swallowing
- drowsiness
- confusion
- mood changes
- trouble controlling body movement (involuntary movement) and weakness in muscles of the arms and legs
- seizures

You or a family member should tell your healthcare provider right away if you have any of these symptoms even if they begin later in treatment. Also tell your healthcare provider about any other new symptoms while taking tolvaptan tablets.

You may be more at risk for ODS if you have:

- liver disease
- not eaten enough for a long period of time (malnourished)
- very low sodium level in your blood
- been drinking large amounts of alcohol for a long period of time (chronic alcoholism)

To lessen your risk of ODS while taking tolvaptan tablets:

- **Treatment with tolvaptan tablets should be started and re-started only in a hospital, where the sodium levels in your blood can be checked closely.**
- Do not take tolvaptan tablets if you cannot tell if you are thirsty.
- To prevent losing too much body water (dehydration), have water available to drink at all times while taking tolvaptan tablets. Unless your healthcare provider tells you otherwise, drink when you are thirsty.
- If your healthcare provider tells you to keep taking tolvaptan tablets after you leave a hospital, it is important that you do not stop and re-start tolvaptan tablets on your own. You may need to go back to a hospital to re-start tolvaptan tablets. Talk to your healthcare provider right away if you stop taking tolvaptan tablets for any reason.
- It is important to stay under the care of your healthcare provider while taking tolvaptan tablets and follow their instructions.

##### 2) Tolvaptan tablets may cause liver problems, including life-threatening liver failure.

Tolvaptan tablets should not be taken for more than 30 days. Tell your doctor right away if you develop or have worsening of any of these signs and symptoms of liver problems:

- Loss of appetite, nausea, vomiting
- Fever, feeling unwell, unusual tiredness
- Itching
- Yellowing of the skin or the whites of the eyes (jaundice)
- Unusual darkening of the urine
- Right upper stomach area pain or discomfort

##### 3) If you have autosomal dominant polycystic kidney disease (ADPKD), do not use tolvaptan tablets because you should receive the medicine (tolvaptan) through a program that ensures laboratory monitoring of your liver.

#### What is tolvaptan tablet?

Tolvaptan tablets are a prescription medicine used to help increase low sodium levels in the blood, in adults with conditions such as heart failure, and certain hormone imbalances. Tolvaptan tablets help raise salt levels in your blood by removing extra body water as urine.

It is not known if tolvaptan tablets are safe or works in children.

#### Who should not take tolvaptan tablets?

Do not take tolvaptan tablets if:

- you are allergic to tolvaptan or any of the ingredients in tolvaptan tablets. See the end of this Medication Guide for a complete list of ingredients in tolvaptan tablets.
- the sodium level in your blood must be increased right away.
- you cannot replace fluids by drinking or you cannot feel if you are thirsty.
- you are dizzy, faint, or your kidneys are not working normally because you have lost too much body fluid.
- you take certain medicines. These medicines could cause you to have too much tolvaptan in your blood:
  - the antibiotic medicines, clarithromycin (Biaxin, Biaxin XL) or telithromycin (Ketek)
  - the antifungal medicines, ketoconazole (Nizoral) or itraconazole (Sporanox)
  - the anti-HIV medicines, ritonavir (Kaletra, Norvir), indinavir (Crixivan), nelfinavir (Viracept), and saquinavir (Invirase)
  - the antidepressant medicine, nefazodone hydrochloride
- your body is not able to make urine. Tolvaptan tablets will not help your condition.

#### What should I tell my healthcare provider before taking tolvaptan tablets?

Tell your healthcare provider about all your medical conditions, including if you:

- have kidney problems and your body cannot make urine.
- have liver problems
- cannot feel if you are thirsty. See "What is the most important information I should know about tolvaptan tablets?"

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- have any allergies. See the end of this Medication Guide for a list of the ingredients in tolvaptan tablets.
- are pregnant or plan to become pregnant. It is not known if tolvaptan tablets will harm your unborn baby.
- are breast-feeding. It is not known if tolvaptan passes into your breast milk. You and your healthcare provider should decide if you will take tolvaptan tablets or breast-feed. You should not do both.
- are taking desmopressin (dDAVP).

**Tell your healthcare provider about all the medicines you take**, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Using tolvaptan tablets with certain medicines could cause you to have too much tolvaptan in your blood. See “Who should not take tolvaptan tablets?”

Tolvaptan tablets may affect the way other medicines work, and other medicines may affect how tolvaptan tablets work.

Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

**How should I take tolvaptan tablets?**

- See “What is the most important information I should know about tolvaptan tablets?”
- Take tolvaptan tablets exactly as prescribed by your healthcare provider.
- Take tolvaptan tablets one time each day.
- You can take tolvaptan tablets with or without food.
- Do not drink grapefruit juice during treatment with tolvaptan tablets. This could cause you to have too much tolvaptan in your blood.
- Certain medicines or illnesses may keep you from drinking fluids or may cause you to lose too much body fluid, such as vomiting or diarrhea. If you have these problems, call your healthcare provider right away.
- Do not miss or skip doses of tolvaptan tablets. If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose. Just take the next dose at your regular time. Do not take 2 doses at the same time.
- **If you take too much tolvaptan tablets, call your healthcare provider right away.** If you take an overdose of tolvaptan tablets, you may need to go to a hospital.
- If your healthcare provider tells you to stop taking tolvaptan tablets, follow their instructions about limiting the amount of fluid you should drink.

**What are the possible side effects of tolvaptan tablets?**

**Tolvaptan tablets can cause serious side effects including:**

- **See “What is the most important information I should know about tolvaptan tablets?”**
- **Loss of too much body fluid (dehydration).** Tell your healthcare provider if you:

- have vomiting or diarrhea, and cannot drink normally.
- feel dizzy or faint. These may be symptoms that you have lost too much body fluid.

Call your healthcare provider right away, if you have any of these symptoms.

The most common side effects of tolvaptan tablets are:

- thirst
- dry mouth
- weakness
- constipation
- making large amounts of urine and urinating often
- increased blood sugar levels

These are not all the possible side effects of tolvaptan tablets. Talk to your healthcare provider about any side effect that bothers you or that does not go away while taking tolvaptan tablets.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**How should I store tolvaptan tablets?**

Store tolvaptan tablets between 68°F to 77°F (20°C to 25°C).

**Keep tolvaptan tablets and all medicines out of the reach of children.**

**General Information about tolvaptan tablets**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use tolvaptan tablets for a condition for which it was not prescribed. Do not give tolvaptan tablets to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about tolvaptan tablets. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about tolvaptan tablets that is written for healthcare professionals.

For more information, call Annora Pharma Private Limited at 1-866-495-1995.

**What are the ingredients in tolvaptan tablets?**

Active ingredient: tolvaptan.

Inactive ingredients: corn starch, croscarmellose sodium, lactose monohydrate, magnesium stearate, methyl alcohol, methylene chloride, microcrystalline cellulose and povidone. FD&C Blue No # 2/Indigo carmine aluminum lake as colorant.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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