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## Tolvaptan (low blood sodium)

pronounced as (tol vap' tan)

### IMPORTANT WARNING:

Tolvaptan (Samsca) may cause the level of sodium in your blood to increase too quickly. This may cause osmotic demyelination syndrome (ODS; serious nerve damage that may be caused by quick increases in sodium levels). Tell your doctor if you drink or have ever drunk large amounts of alcohol, if you have malnutrition (the body lacks the nutrients needed for good health), and if you have or have ever had liver disease or extremely low levels of sodium in your blood.

You and your doctor will take certain precautions to try to prevent ODS. You will begin your treatment with tolvaptan (Samsca) in the hospital so that your doctor can monitor you closely. If your doctor tells you to continue taking tolvaptan (Samsca) after you leave the hospital, you should not stop and re-start treatment on your own. You will need to return to the hospital when you restart the medication.

You will need to drink water whenever you are thirsty to help prevent ODS during your treatment with tolvaptan (Samsca) . Your doctor will not prescribe tolvaptan (Samsca) if you are unable to feel that you are thirsty. You should have drinking water available at all times during your treatment.

If you experience any of the following symptoms of ODS, tell your doctor immediately: difficulty speaking, difficulty swallowing, feeling that food or drinks are getting stuck in your throat, drowsiness, confusion, mood changes, body movements that are difficult to control, weakness of the arms or legs, or seizures.

You should know that tolvaptan is also available as a tablet (Jynarque) to slow the worsening of kidney function in adults with a certain type of inherited kidney disease. If you have this kidney disease, you should not take tolvaptan (Samsca). Because of the risk of liver problems with tolvaptan, Jynarque is available only through a special restricted distribution program. This monograph only gives information about tolvaptan tablets (Samsca) to treat low levels of sodium in the blood. If you are using this medication to slow the worsening of your kidney function, read the monograph entitled tolvaptan (kidney disease).

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with tolvaptan and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit

the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>] ) or the manufacturer's website to obtain the Medication Guide.

Talk to your doctor about the risk of taking tolvaptan (Samsca).

## Why is this medication prescribed?

Tolvaptan (Samsca) is used to treat hyponatremia (low levels of sodium in the blood) in people who have heart failure (condition in which the heart cannot pump enough blood to all parts of the body), syndrome of inappropriate antidiuretic hormone (SIADH; condition in which the body produces too much of a certain natural substance that causes the body to retain water) or other conditions. Tolvaptan is in a class of medications called vasopressin V<sub>2</sub> receptor antagonists. It works by increasing the amount of water released from the body as urine. Removing fluid from the body helps to increase the level of sodium in the blood.

## How should this medicine be used?

Tolvaptan (Samsca) comes as a tablet to take by mouth. It is usually taken once a day with or without food for no longer than 30 days. At the beginning of your treatment, you will be given tolvaptan (Samsca) at a regularly scheduled time in the hospital. If you are told to take tolvaptan (Samsca) at home after you are discharged, you should take it at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take tolvaptan (Samsca) exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Your doctor will probably start you on a low dose of tolvaptan (Samsca) and gradually increase your dose, not more often than once every 24 hours.

Talk to your doctor about what you should do after you stop taking tolvaptan (Samsca). You will probably need to limit the amount of fluid you drink, and your doctor will monitor you carefully during this time.

## Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

## What special precautions should I follow?

### Before taking tolvaptan (Samsca),

- tell your doctor and pharmacist if you are allergic to tolvaptan (Samsca, Jynarque) , any other medications, or any of the ingredients in tolvaptan tablets. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor if you are taking certain antifungals such as ketoconazole (Nizoral) or itraconazole (Sporanox); clarithromycin (Biaxin); certain medications for HIV such as indinavir (Crixivan), nelfinavir (Viracept), ritonavir (Norvir), or saquinavir (Invirase); desmopressin (dDAVP, Stimate); nefazodone; or

telithromycin (Ketek). Your doctor may tell you not to take tolvaptan (Samsca) if you are taking one or more of these medications.

- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, and nutritional supplements you are taking or plan to take. Be sure to mention any of the following: angiotensin-converting enzyme (ACE) inhibitors such as benazepril (Lotensin, in Lotrel), captopril, enalapril (Vasotec, in Vaseretic), fosinopril, lisinopril (Prinivil, Zestril, in Zestoretic), moexipril, perindopril, (quinapril (Accupril, in Accuretic, in Quinaretic), ramipril (Altace), andtrandolapril (Tarka); angiotensin II receptor blockers such as candesartan (Atacand), eprosartan, irbesartan (Avapro, in Avalide), losartan (Cozaar, in Hyzaar), olmesartan (Benicar, in Benicar HCT, in Tribenzor), telmisartan (Micardis, in Twynsta), and valsartan (Diovan, Prexxartan, in Entresto, in Exforge); aprepitant (Emend); barbiturates such as phenobarbital; carbamazepine (Carbatrol, Equetro, Tegretol); cyclosporine (Gengraf, Neoral, Sandimmune); desmopressin (dDAVP, Minirin, Noctiva), digoxin (Lanoxin); diltiazem (Cardizem, Diltzac, Tiazac); diuretics (water pills); erythromycin (E.E.S., ERYC, Erythrocin, PCE); fluconazole (Diflucan); phenytoin (Dilantin); potassium supplements; rifabutin (Mycobutin); rifampin (Rimactane, Rifadin, in Rifater, in Rifamate); rifapentine (Priftin); and verapamil (Calan, Verelan, in Tarka). Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with tolvaptan (Samsca), so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.
- tell your doctor what herbal products you are taking or plan to take, especially St John's wort.
- tell your doctor if you have kidney disease and do not produce urine, if you have severe vomiting or diarrhea, or if you have lost a lot of fluid from your body and feel dizzy or faint. Your doctor will probably tell you not to take tolvaptan (Samsca). Your doctor will also probably not prescribe tolvaptan (Samsca) if your sodium level must be increased very quickly.
- tell your doctor if you have or have ever had a high level of potassium in your blood.
- tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. If you become pregnant while taking tolvaptan (Samsca), call your doctor.

## What special dietary instructions should I follow?

Do not eat grapefruit or drink grapefruit juice while taking this medication.

## What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

## What side effects can this medication cause?

**Tolvaptan (Samsca) may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:**

- thirst
- dry mouth
- frequent, excessive urination
- constipation

**Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately:**

- loss of appetite
- nausea
- vomiting
- fever
- feeling unwell
- unusual tiredness or weakness
- itching
- yellowing of the skin or eyes
- dark urine
- pain in the upper right part of the stomach
- diarrhea
- inability to drink normally
- dizziness
- faintness
- vomit that is bloody or looks like coffee grounds
- bloody or black and tarry stools
- swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs
- hoarseness
- hives
- rash

Tolvaptan (Samsca) may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>] ) or by phone (1-800-332-1088).

## **What should I know about storage and disposal of this medication?**

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the

best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>] ) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

## In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

## Symptoms of overdose may include the following:

- excessive urination
- excessive thirst
- dizziness
- faintness

## What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor may order certain lab tests to check your body's response to tolvaptan (Samsca).

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

## Brand names

- Samsca<sup>®</sup>

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National Library of Medicine 8600 Rockville Pike, Bethesda, MD 20894 U.S. Department of Health and Human Services

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