Package leaflet: Information for the user

Samsca 7.5 mg tablets
Samsca 15 mg tablets
Samsca 30 mg tablets
tolvaptan

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Samsca is and what it is used for

Samsca, which contains the active substance tolvaptan, belongs to a group of medicines called vasopressin antagonists. Vasopressin is a hormone that helps prevent the loss of water from the body by reducing urine output. Antagonist 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 or concentration of sodium in your blood.

Samsca is used to treat low serum sodium levels in adults. You have been prescribed this medicine because you have a lowered sodium level in your blood as a result of a disease called “syndrome of inappropriate antidiuretic hormone secretion” (SIADH) where the kidneys retain too much water. This disease causes an inappropriate production of the hormone vasopressin which has caused the sodium levels in your blood to get too low (hyponatremia). That can lead to difficulties in concentration and memory, or in keeping your balance.

2. What you need to know before you take Samsca

Do not take Samsca
- if you are allergic to tolvaptan or any of the other ingredients of this medicine (listed in section 6) or if you are allergic to benzazepine or benzazepine derivatives (e.g. benazepril, conivaptan, fenoldopam mesylate or mirtazapine)
- if your kidneys do not work (no urine production)
- if you have a condition which increases the salt in your blood (“hypernatremia”)
- 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 breast-feeding.

Warnings and precautions
Talk to your doctor or pharmacist before taking Samsca:

- 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 had an allergic reaction in the past to benzazepine, tolvaptan or other benzazepine derivatives (e.g. benazepril, conivaptan, fenoldopam mesylate or mirtazapine), or to any of the other ingredients of this medicine (listed in section 6).
- if you suffer from a kidney disease called autosomal dominant polycystic kidney disease (ADPKD)
- if you have diabetes.

Drinking enough water
Samsca 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 and adolescents
Samsca is not suitable for children and adolescents (under age 18).

Other medicines and Samsca
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes all medicines obtained without a prescription.

The following medicines may increase the effect of this medicine:
- ketoconazole (against fungal infections),
- macrolide antibiotics,
- diltiazem (treatment for high blood pressure and chest pain),
- other products which increase the salt in your blood or which contain large amounts of salt.

The following medicines may lower the effect of this medicine:
- barbiturates (used to treat epilepsy/seizures and some sleep disorders),
- rifampicin (against tuberculosis).

This medicine may increase the effect of the following medicines:
- digoxin (used for treatment of irregularities of heart beat and heart failure).

This medicine may lower the effect of the following medicines:
- desmopressin (used to increase blood clotting factors).

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

Samsca with food and drink
Avoid drinking grapefruit juice when taking Samsca.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take this medicine if you are pregnant or breast-feeding.

Adequate contraceptive measures must be used during use of this medicine.

Driving and using machines
Samsca is unlikely to adversely affect your ability to drive or to operate machinery. However, you may occasionally feel dizzy or weak or you may faint for a short period.

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

3. How to take Samsca

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Treatment with Samsca will be initiated in hospital.
- For treatment of your low sodium (hyponatremia), 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 Samsca your doctor will do regular blood tests. To achieve the desired level of serum sodium your doctor can give in some instances a lower dose of 7.5 mg.
- 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 Samsca 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 Samsca
If you forget to take your medicine you have to 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 a forgotten dose.

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

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

4. Possible side effects

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

If you notice any of the following side effects, you may need urgent medical attention. Stop taking Samsca 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 (symptoms of an allergic reaction).

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

Other side effects

Very common (may affect more than 1 in 10 people)
- feeling sick
- thirst
- rapid rise in level of sodium.

Common (may affect up to 1 in 10 people)
- excessive drinking of water
- water loss
- high levels of sodium, potassium, creatinine, uric acid and blood sugar
- decrease in level of blood sugar
- decreased appetite
- fainting
- headache
- dizziness
- low blood pressure when standing up
- constipation
- diarrhoea
- dry mouth
- patchy bleeding in the skin
- itching
- increased need to urinate, or to urinate more frequently
- tiredness, general weakness
- fever
- general feeling of being unwell
- blood in urine
- raised levels of liver enzymes in the blood
- raised levels of creatinine in the blood.

Uncommon (may affect up to 1 in 100 people)
- sense of taste altered
- kidney problems

Not known (cannot be estimated from the available data)
- allergic reactions (see above)
- liver problems
- acute liver failure (ALF)
- increase in liver enzymes.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Samsca

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and 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.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Samsca contains

- The active substance is tolvaptan
  Each Samsca 7.5 mg tablet contains 7.5 mg tolvaptan.
  Each Samsca 15 mg tablet contains 15 mg tolvaptan.
  Each Samsca 30 mg tablet contains 30 mg tolvaptan.

- The other ingredients are lactose monohydrate, maize starch, microcrystalline cellulose, hydroxypropylcellulose, magnesium stearate, indigo carmine aluminium lake (E 132).

What Samsca looks like and contents of the pack
Samsca 7.5 mg: Blue, rectangular, shallow-convex tablets with dimensions of 7.7 × 4.35 × 2.5 mm, debossed with "OTSUKA" and "7.5" on one side.
Samsca 15 mg: Blue, triangular, shallow-convex tablets with dimensions of 6.58 × 6.2 × 2.7 mm, debossed with "OTSUKA" and "15" on one side.
Samsca 30 mg: Blue, round, shallow-convex tablets with dimensions of Ø8 × 3.0 mm, debossed with "OTSUKA" and "30" on one side.

Samsca 7.5 mg tablets are available as
10 tablets in PP/Alu blisters
30 tablets in PP/Alu blisters
10 × 1 tablet in PVC/Alu perforated unit dose blisters
30 × 1 tablet in PVC/Alu perforated unit dose blisters

Samsca 15 mg and Samsca 30 mg tablets are available as
10 × 1 tablet in PVC/Alu perforated unit dose blisters
30 × 1 tablet in PVC/Alu perforated unit dose blisters

Not all pack sizes may be marketed.

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.