

SAMSCA®

Tolvaptan 15 mg tablets

Consumer Medicine Information

What is this leaflet?

Please read this leaflet carefully before you start using SAMSCA.

This leaflet answers some common questions about SAMSCA.

It does not contain all of the available information. Reading this leaflet does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of your taking SAMSCA against the benefits they expect it will have for you.

If you have any concerns about taking SAMSCA, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may want to read it again.

What SAMSCA is used for

SAMSCA contains tolvaptan and is used to treat hyponatraemia in adults, including patients who have conditions such as heart failure, and "syndrome of inappropriate antidiuretic hormone secretion" (SIADH). These conditions result in an inappropriate amount of the hormone vasopressin causing 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.

SAMSCA 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 concentration of sodium in your blood.

Ask your doctor if you have any questions about why SAMSCA has been prescribed for you.

Your doctor may have prescribed it for another use.

SAMSCA is not addictive.

SAMSCA is only available on a doctor's prescription.

Before you take SAMSCA

When you must not take it

Do not take this medicine if you have an allergy to:

- any medicine containing tolvaptan
- any of the other ingredients listed at the end of this leaflet
- any other similar medicine such as benzapine derivatives

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine if you have any of the following medical conditions:

- you cannot replace fluids by drinking
- you cannot feel if you are thirsty

- you have a condition which is associated with a very low blood volume
- you are not producing or passing urine

Do not take this medicine if you are taking the following medicine(s):

- medicines to treat fungal infections such as ketoconazole or itraconazole
- medicines to treat bacterial infections such as clarithromycin or telithromycin
- medicines to treat HIV infection such as saquinavir, nelfinavir or ritonavir
- medicines to treat depression i.e. nefazodone.

Do not take this medicine if you need to increase the sodium level in your blood right away.

The safety and efficacy in these patients has not been studied.

Do not take this medicine after the expiry date on the pack or if the packaging is torn or seems to have been opened.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- you cannot drink enough water or you are fluid restricted

- difficulties in urination or have an enlarged prostate
- liver disease including cirrhosis
- diabetes
- hypothyroidism (an underactive thyroid gland)
- hypoadrenalism (an underactive adrenal gland).

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

It is not known if SAMSCA will harm your unborn baby or if it passes into breast milk.

This medicine contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars, tell your doctor before taking SAMSCA.

If you have not told your doctor about any of the above, tell him/her before you start taking SAMSCA.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Certain medicines may be affected by SAMSCA or may affect how well it works. These include:

- medicines to treat fungal infections such as ketoconazole, itraconazole or fluconazole
- macrolide antibiotics such as clarithromycin or telithromycin or erythromycin
- treatments for high blood pressure and chest pain such as diltiazem or verapamil
- treatments of irregularities of heart beat and heart failure such as digoxin
- treatments for epilepsy/seizures and some sleep disorders such as barbiturates, phenytoin or carbamazepine
- medicines to treat tuberculosis such as rifampicin rifabutin or rifapentin

- medicines to immunosuppressant therapy such as cyclosporine
- treatments used to prevent or control bleeding, i.e. vasopressin analogs
- treatments of HIV infection such as saquinavir, nelfinavir or ritonavir; and
- medicines used to treat depression, i.e. nefazodone or St. John's Wort.
- other medicines that increase the level of sodium in your blood or which contain large amounts of salt, such as tablets that dissolve in water and indigestion remedies

These medicines may be affected by SAMSCA or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor will have more information on medicines to be careful with or avoid while taking SAMSCA.

How to take SAMSCA

Treatment with SAMSCA should be started and re-started only in a hospital, where the sodium levels in your blood can be monitored closely.

If your doctor or pharmacist tells you to keep taking SAMSCA after you leave a hospital, it is important that you do not stop and restart SAMSCA on your own.

You may need to go back to a hospital to re-start SAMSCA. Talk to your doctor right away if you stop taking SAMSCA for any reason.

It is important to stay under the care of your doctor while taking SAMSCA and follow their instructions.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

Take SAMSCA once a day.

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.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, SAMSCA may not work as well and your problem may not improve.

Do not take more than the dose your doctor has recommended.

How to take it

You can take SAMSCA with or without food.

Tablets should be swallowed without chewing and with a glass of water.

Do not take SAMSCA with grapefruit juice.

When to take it

Take your SAMSCA the same time each day, preferably in the morning.

This will help you remember when to take the medicine.

Certain medicines or illnesses may keep you from drinking fluids or may cause you to lose too much body fluid, such as vomiting or diarrhoea. If you have these problems, call your doctor right away.

How long to take it

Continue taking SAMSCA for as long as your doctor tells you.

SAMSCA should not be taken for longer than 30 days.

If you forget to take it

Do not miss or skip doses of SAMSCA.

If you miss a dose, take it as soon as you remember and then go back to taking your medicine as you would normally.

If it is almost the time of the next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much SAMSCA. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Remember to take the medicine pack with you so that it is clear what you have taken.

Symptoms of an overdose may include:

- thirst
- dehydration
- passing more urine than normal
- low blood volume causing very low blood pressure
- a rise in concentration of sodium concentration the blood

If your doctor tells you to stop taking SAMSCA, follow their instructions about limiting the amount of fluid you should drink.

While you are taking SAMSCA

Things you must do

Make sure you have access to water and continue to drink when thirsty.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking SAMSCA.

Tell any other doctors, dentists and pharmacists who treat you that you are taking SAMSCA.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Things you must not do

Do not use SAMSCA to treat any complaint other than that directed by your doctor.

Do not give SAMSCA to someone else even if their symptoms are the same.

Do not stop taking SAMSCA or lower the dose unless you notice side effects requiring urgent medical attention or if your doctor tells you to do so.

This may lead to reoccurrence of your low sodium.

Things to be careful of

Drinking enough water

Samsca causes water loss because it increases your urine production.

This water loss commonly results in dry mouth and thirst, and less commonly severe side effects such as kidney problems. It is therefore important that you have access to water and that you are able to drink sufficient amounts when you feel thirsty.

Be careful when driving, operating machinery or doing jobs that require you to be alert until you know how this medicine affects you.

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

Side Effects

The following effects are likely to be experienced by most people taking SAMSCA. However, tell your doctor if they worry you.

- thirst
- dry mouth
- making large amounts of urine and urinating often.

Tell your doctor as soon as possible if you feel unwell while you are taking SAMSCA.

This medicine helps most people with hyponatraemia but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- weakness
- constipation
- increased blood sugar levels
- have vomiting or diarrhoea, and cannot drink normally
- feel dizzy or faint. These may be symptoms that you have lost too much body fluid
- fever
- loss of appetite
- nausea.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- difficulty swallowing
- difficulty speaking
- lethargy/fatigue (tiredness)
- mood changes
- difficulty moving arms or legs, or uncontrollable movements
- seizures or convulsions
- you vomit bright red blood
- you vomit dark blood clots, or material that looks like coffee-grounds
- you pass blood or stool mixed with blood.

Samsca may affect your liver function. Therefore, please inform your doctor at any time if you have signs that could indicate potential liver problems such as:

- unusual exhaustion
- loss of appetite
- pain in your right upper stomach
- dark urine
- jaundice (yellowing of your skin or the whites of your eyes)

During treatment with Samsca, your doctor may arrange blood tests to check for changes in your liver function or electrolytes (salts).

Talk to your doctor about any side effect that bothers you or that does not go away while taking SAMSCA.

The side effects listed above are not all the possible side effects of SAMSCA.

After using SAMSCA

Storage

Store SAMSCA below 25°C and away from light and moisture.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot or cold days. Heat, cold and dampness can destroy some medicines.

Keep SAMSCA where children cannot reach it.

A locked cupboard at least one-and-a-half metre above the ground is a good place to store medicines.

Keep SAMSCA in the pack until it is time to take your dose. If it is removed from the pack, it may not keep well.

Disposal

If your doctor tells you to stop taking SAMSCA or the expiry date has passed, ask your doctor what to do with any SAMSCA that is left over.

Product description

What SAMSCA looks like

SAMSCA is supplied as 15 mg tablets in a PVC/aluminium perforated unit dose blister pack of 10 tablets.

The 15 mg tablet is blue, triangular, shallow-convex, debossed with "OTSUKA" and "15" on one side.

Ingredients

SAMSCA tablets contain 15 mg of the active ingredient, tolvaptan. It also contains the following inactive ingredients:

- maize starch
- hydroxypropylcellulose
- lactose monohydrate
- magnesium stearate
- microcrystalline cellulose
- indigo carmine (E 132) aluminium lake as colorant.

Manufacturer/Supplier

SAMSCA is supplied in Australia by:

Otsuka Australia Pharmaceutical Pty Ltd
Suite 2.03, Level 2

9 Help Street
Chatswood NSW 2067,

This leaflet was prepared in January 2018

Australian Registration Number:
AUST R 176602

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