

PART III: CONSUMER INFORMATION

PrSAMSCA®

Tolvaptan Tablets

This leaflet is part III of a three-part "Product Monograph" published when SAMSCA was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about SAMSCA. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

SAMSCA is a prescription medicine used to help increase low sodium levels in the blood, in adults with conditions such as heart failure, liver disease, and certain hormone imbalances.

What it does:

SAMSCA helps raise salt levels in your blood by removing extra body water as urine.

When it should not be used:

Do not take SAMSCA if:

- you are allergic or hypersensitive to tolvaptan, benzazepine or benzazepine derivatives, (e.g. REMERON®) or any of the ingredients in SAMSCA.
 - your kidneys do not work (no urine production)
 - you have a condition which increases the sodium in your blood
 - you cannot replace fluids by drinking or you can not 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 SAMSCA in your blood:
 - the antibiotic medicines, clarithromycin or telithromycin
 - the antifungal medicines, ketoconazole or itraconazole
 - the anti-HIV medicines, ritonavir, indinavir, nelfinavir, and saquinavir
 - the antidepressant medicine, nefazodone
 - your body is not able to make any urine. SAMSCA® will not help your condition
 - you are pregnant
 - you are breast-feeding
 - you have one of the following rare hereditary diseases:
 - Galactose intolerance
 - Lapp lactase deficiency
 - Glucose-galactose malabsorption
- Lactose is a non-medicinal ingredient in SAMSCA.

It is not known if SAMSCA is safe or works in children.

What the medicinal ingredient is:

tolvaptan

What the non-medicinal ingredients are:

Corn starch, hydroxypropyl cellulose, lactose monohydrate, low-substituted hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, and FD&C Blue No. 2 Aluminum Lake as colorant.

What dosage forms it comes in:

Tablets: 15 mg, 30 mg, and 60 mg

WARNINGS AND PRECAUTIONS

SAMSCA 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

SAMSCA use may cause liver injury when used at much higher doses (twice as high) than those recommended for treatment of low sodium levels in the blood. SAMSCA should not be used at higher doses than those recommended, or longer than necessary. During treatment with SAMSCA, your doctor will arrange blood tests to check for changes in your liver function, as follows:

- before starting treatment with SAMSCA
- every month for the first 18 months, then
- every 3 months for the next 12 months, and
- every 3 - 6 months thereafter during treatment

In post-marketing experience, anaphylaxis (including anaphylactic shock and generalised rash) has been reported very rarely following administration of SAMSCA. This type of reaction can occur after the first administration of tolvaptan. You will be carefully monitored during treatment. If an anaphylactic reaction or other serious allergic reaction occur, your treatment with SAMSCA must be stopped immediately and you may require treatment. If this happens, seek immediate medical attention. If you have an

anaphylactic or hypersensitivity reaction to SAMSCA, you should not be given SAMSCA again.

Patients with known hypersensitivity reactions to benzazepines or benzazepine derivatives (e.g. mirtazapine) may be at risk for a hypersensitivity reaction to tolvaptan. Your doctor will discontinue treatment with SAMSCA if they suspect you are having a hypersensitivity reaction.

To prevent pregnancy while on SAMSCA, women of childbearing potential should have effective contraceptive measures in place before and during treatment.

BEFORE you use SAMSCA talk to your doctor or pharmacist if you:

- have any allergies
- have liver disease
- have not eaten enough for a long period of time (malnourished)
- have been drinking large amounts of alcohol for a long period of time (chronic alcoholism)

INTERACTIONS WITH THIS MEDICATION

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

Using SAMSCA with certain medicines could cause you to have too great of a drug effect with SAMSCA in your blood.

SAMSCA may affect the way other medicines work, and other medicines may affect how SAMSCA works.

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.

SAMSCA should not be taken by patients who are also taking:

- clarithromycin, telithromycin, ketoconazole, itraconazole, ritonavir, indinavir, nelfinavir, saquinavir, nefazodone,
- vasopressin drugs, such as desmopressin, used to control bleeding.

Avoid taking SAMSCA if you are also taking:

- erythromycin, fluconazole, aprepitant, diltiazem and verapamil

The following may interact with SAMSCA and lower its effect:

- rifampin, rifabutin, rifapentin, barbiturates, phenytoin, carbamazepine and St. John's Wort

PROPER USE OF THIS MEDICATION

Usual dose:

- Take SAMSCA once daily as directed by your doctor.
- You can take SAMSCA with or without food.
- Do not drink grapefruit juice during treatment with SAMSCA. This could cause you to have too great of a drug effect.
- 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.
- To prevent losing too much body water (dehydration), have water available to drink at all times while taking SAMSCA. Unless your healthcare provider tells you otherwise, drink when you are thirsty.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

Do not miss or skip doses of SAMSCA. 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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects of SAMSCA are:

- Thirst
- Dry mouth
- Weakness
- Increased amount of urine
- Increased frequency of urination during the day and at night
- Constipation

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Common	Large amounts of urine and more frequent urination	√		
	High levels of sugar in blood	√		
Uncommon	Signs of dehydration including vomiting, dizziness, diarrhea, or cannot drink normally			√
	Bleeding from the gastrointestinal tract (symptoms such as blood in stool or vomit, black stool)			√
Unknown	Liver Injury (symptoms like fatigue, anorexia, right upper abdominal discomfort, dark urine, or jaundice)			√

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: www.otsukacanada.com or by contacting the marketer, Otsuka Canada Pharmaceutical Inc. at: 1-877-341-9245.

If you have any questions about this product, please contact OCPI at: 1-877-341-9245.

This leaflet was prepared by Otsuka Pharmaceutical Co., Ltd.

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This is not a complete list of side effects. For any unexpected effects while taking SAMSCA, contact your doctor or pharmacist.

HOW TO STORE IT

Store SAMSCA between 15°C to 30°C.

Keep SAMSCA out of sight and reach of children.