EMA/416573/2018
EMEA/H/C/000980

Samsca (*tolvaptan*)

An overview of Samsca and why it is authorised in the EU

What is Samsca and what is it used for?

Samsca is a medicine for treating abnormally low levels of sodium in the blood in adults with a condition called 'syndrome of inappropriate antidiuretic hormone secretion' (SIADH).

In SIADH, an excessive amount of the hormone vasopressin makes the patient produce less urine and thereby retain more water in the body, which dilutes the concentration of sodium in the blood.

Samsca contains the active substance tolvaptan.

How is Samsca used?

Samsca is available as tablets (7.5, 15 and 30 mg). The starting dose is 15 mg once a day. This may be increased to a maximum of 60 mg once a day to achieve an appropriate level of blood sodium and blood volume. A dose of 7.5 mg once a day can be used for patients at risk of excessively quick rise in blood sodium.

The medicine can only be obtained with a prescription. Treatment with Samsca should be started in hospital so that healthcare professionals can determine the most appropriate dose and monitor the patient's level of blood sodium and blood volume.

For more information about using Samsca, see the package leaflet or contact your doctor or pharmacist.

How does Samsca work?

People with SIADH have an excessive amount of vasopressin, leading to decreased urine production and dilution of the blood. The active substance in Samsca, tolvaptan, is a 'vasopressin-2 receptor antagonist'. This means that it blocks one type of receptor (target) to which the hormone vasopressin normally attaches itself. By blocking this receptor, Samsca prevents vasopressin's effect. This increases urine production, decreasing the amount of water in the blood and increasing the blood sodium level.

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What benefits of Samsca have been shown in studies?

Two studies involving 424 adults showed that Samsca is effective at increasing sodium levels in patients with low levels caused by SIADH and other conditions such as liver and heart problems. However, Samsca was more effective in patients with SIADH than in those with liver or heart problems. Normal sodium levels are between 135 and 145 mmol/l.

In patients with SIADH, sodium levels, which were around 129 mmol/l at the start of treatment, rose by an average of 4.8 mmol/l by day 4 in those who took Samsca, compared with 0.2 mmol/l in those who took placebo (dummy treatment). By day 30, sodium had increased by an average of 7.4 mmol/l in patients who took Samsca, compared with 1.5 mmol/l in patients receiving placebo.

What are the risks associated with Samsca?

The most common side effects with Samsca (which may affect more than 1 patient in 10) are thirst, nausea (feeling sick) and sodium levels rising too quickly. For the full list of side effects reported with Samsca, see the package leaflet.

Samsca must not be used in patients with anuria (an inability to pass urine), very low blood volume, low blood sodium levels with low blood volume, hypernatremia (abnormally high levels of sodium in the blood) or in patients who cannot perceive thirst. It must not be used in patients who are allergic to tolvaptan or medicines that are similar to tolvaptan, so-called benzazepines or their derivatives. Samsca must also not be used in women who are pregnant or breast-feeding. For the full list of restrictions, see the package leaflet.

Why is Samsca authorised in the EU?

Samsca has been shown to be effective at increasing sodium levels, particularly in patients with SIADH. The only major safety concerns seen with this medicine came from animal studies suggesting it could be harmful to unborn babies. This medicine must therefore not be used in women who are pregnant or breastfeeding.

The European Medicines Agency concluded that Samsca's benefits are greater than its risks and that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Samsca?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Samsca have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Samsca are continuously monitored. Side effects reported with Samsca are carefully evaluated and any necessary action taken to protect patients.

Other information about Samsca

Samsca received a marketing authorisation valid throughout the European Union on 3 August 2009.

Further information on Samsca can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

This overview was last updated in 06-2018