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Tolvaptan Accord (tolvaptan)

An overview of Tolvaptan Accord and why it is authorised in the EU

What is Tolvaptan Accord and what is it used for?

Tolvaptan Accord 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 people with SIADH, an excessive amount of the hormone vasopressin makes them produce less urine and thereby retain more water in the body, which dilutes the concentration of sodium in the blood.

Tolvaptan Accord is a 'generic medicine'. This means that Tolvaptan Accord contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for Tolvaptan Accord is called Samsca. For more information on generic medicines, see the question-and-answer document here.

Tolvaptan Accord contains the active substance tolvaptan.

How is Tolvaptan Accord used?

Tolvaptan Accord is given once a day as a tablet. The medicine can only be obtained with a prescription. Treatment 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 Tolvaptan Accord, see the package leaflet or contact your doctor or pharmacist.

How does Tolvaptan Accord work?

People with SIADH have an excessive amount of the hormone vasopressin, leading to decreased urine production and an increased amount of water in the blood. The active substance in this medicine, 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, Tolvaptan Accord prevents vasopressin's effect. This increases urine production and decreases the amount of water in the blood, thereby increasing the blood sodium level.

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How has Tolvaptan Accord been studied?

Studies on the benefits and risks of the active substance in the authorised use have already been carried out with the reference medicine, Samsca, and do not need to be repeated for Tolvaptan Accord.

As for every medicine, the company provided studies on the quality of Tolvaptan Accord. The company also carried out a study that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Tolvaptan Accord?

Because Tolvaptan Accord is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Tolvaptan Accord authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Tolvaptan Accord has been shown to have comparable quality and to be bioequivalent to Samsca. Therefore, the Agency's view was that, as for Samsca, the benefits of Tolvaptan Accord outweigh the identified risks and it can be authorised for use in the EU.

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

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

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

Other information about Tolvaptan Accord

Tolvaptan Accord received a marketing authorisation valid throughout the EU on 24 March 2023.

Further information on Tolvaptan Accord can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/tolvaptan-accord. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in March 2023.