EMA/150836/2015
EMEA/H/C/003968

EPAR summary for the public

Tasermity

sevelamer hydrochloride

This is a summary of the European public assessment report (EPAR) for Tasermity. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Tasermity.

For practical information about using Tasermity, patients should read the package leaflet or contact their doctor or pharmacist.

What is Tasermity and what is it used for?

Tasermity is a medicine used to control hyperphosphataemia (high blood phosphate levels) in adult patients on dialysis (a blood clearance technique). It can be used in patients undergoing haemodialysis (using a blood filtration machine) or peritoneal dialysis (where fluid is pumped into the abdomen and an internal body membrane filters the blood).

Tasermity should be used with other treatments such as calcium supplements and vitamin D to prevent the development of bone disease.

Tasermity contains the active substance sevelamer hydrochloride. This medicine is the same as Renagel, which is already authorised in the European Union (EU). The company that makes Renagel has agreed that its scientific data can be used for Tasermity ('informed consent').

How is Tasermity used?

Tasermity is available as tablets (800 mg). The recommended starting dose of Tasermity is 1 or 2 tablets three times a day, depending on clinical need and the level of phosphate in the blood. Tasermity must be taken with meals and patients should keep to their prescribed diets.

The dose of Tasermity should be adjusted every two to three weeks to reach an acceptable level of phosphate in the blood, which should then be monitored regularly.

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The medicine can only be obtained with a prescription.

How does Tasermity work?

Patients with severe kidney disease cannot eliminate phosphate from their bodies. This leads to phosphate accumulating in the body, which, in the long term, can cause complications affecting the heart and the bones. The active substance in Tasermity, sevelamer hydrochloride, is a phosphate binder. When taken with meals, the sevelamer molecules in Tasermity attach in the gut to phosphate from food, preventing it from being absorbed into the body. This helps to reduce the phosphate levels in the blood.

What benefits of Tasermity have been shown in studies?

Studies have shown that Tasermity significantly reduces blood phosphate levels in patients with kidney disease undergoing dialysis.

In a study of 84 patients undergoing haemodialysis, there was an average fall in phosphate levels of 0.65 mmol/l in patients taking Tasermity for 8 weeks, compared with a fall of 0.68 mmol/l in patients taking calcium acetate, another phosphate-lowering medicine. Similar results with Tasermity were seen in another 8-week study involving 172 haemodialysis patients, while in a third longer-term study (over 44 weeks) Tasermity led to an average fall of 0.71 mmol/l.

The benefit of Tasermity has also been shown in a study of 143 patients undergoing peritoneal dialysis: patients receiving Tasermity in this study had similar falls in phosphate levels over 12 weeks as the patients receiving calcium acetate (0.52 and 0.58 mmol/l, respectively).

What are the risks associated with Tasermity?

The most common side effects with Tasermity (which may affect more than 1 in 10 people) are nausea (feeling sick) and vomiting.

Tasermity must not be used in people with hypophosphataemia (low blood phosphate levels) or with bowel obstruction (a blockage in the gut).

For the full list of all side effects and restrictions with Tasermity, see the package leaflet.

Why is Tasermity approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Tasermity's benefits are greater than its risks for the treatment of hyperphosphataemia and recommended that it be approved for use in the EU.

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

A risk management plan has been developed to ensure that Tasermity is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Tasermity, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Tasermity

The European Commission granted a marketing authorisation valid throughout the European Union for Tasermity on 26 February 2015.

The full EPAR for Tasermity can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Tasermity, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 02-2015.