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Sevelamer carbonate Zentiva (*sevelamer carbonate*)

An overview of Sevelamer carbonate Zentiva and why it is authorised in the EU

What is Sevelamer carbonate Zentiva and what is it used for?

Sevelamer carbonate Zentiva is a medicine used to control hyperphosphataemia (high blood phosphate levels) in:

- adult patients on dialysis (a technique to remove unwanted substances from the blood);
- adults and children from 6 years of age with chronic (long-term) kidney disease.

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

It contains the active substance sevelamer carbonate.

How is Sevelamer carbonate Zentiva used?

Sevelamer carbonate Zentiva is available as tablets (800 mg) and as powder (800 mg and 2.4 g) to be taken 3 times a day with meals.

The dose to take depends on the patient's level of blood phosphate and, for children, their height and weight. Sevelamer carbonate Zentiva must not be taken on an empty stomach and patients should keep to their prescribed diets.

The medicine can only be obtained with a prescription. For more information about using Sevelamer carbonate Zentiva, see the package leaflet or contact your doctor or pharmacist.

How does Sevelamer carbonate Zentiva work?

The active substance in Sevelamer carbonate Zentiva, sevelamer carbonate, is a phosphate binder. When taken with meals, it attaches in the gut to phosphate from the food, thereby preventing the phosphate from being absorbed into the body and helping reduce phosphate levels in the blood.

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What benefits of Sevelamer carbonate Zentiva have been shown in studies?

Sevelamer carbonate Zentiva has been shown in studies to be effective at lowering levels of blood phosphate in patients with hyperphosphataemia.

In two main studies in 110 adults with kidney disease who were on dialysis, Sevelamer carbonate Zentiva brought phosphate levels down to around 1.5-1.6 mmol/l (which is within or close to the normal range) and was as effective as another approved medicine Renagel.

In a third main study in 49 adults who were not on dialysis, Sevelamer carbonate Zentiva reduced phosphate levels from 2.0 mmol/l to 1.6 mmol/l.

Finally, a main study also showed that Sevelamer carbonate Zentiva was effective at lowering phosphate levels in 100 children: children who took Sevelamer carbonate Zentiva had a greater reduction in phosphorous (0.87 mg/dl) than those taking placebo (a dummy treatment) who had a rise in phosphorous of 0.04 mg/dl.

What are the risks associated with Sevelamer carbonate Zentiva?

The most common side effects with Sevelamer carbonate Zentiva (which may affect more than 1 in 10 people) are nausea (feeling sick), vomiting, upper abdominal (belly) pain and constipation. For the full list of side effects of Sevelamer carbonate Zentiva, see the package leaflet.

Sevelamer carbonate Zentiva must not be used in people with low blood phosphate levels or with bowel obstruction (a blockage in the gut). For the full list of restrictions, see the package leaflet.

Why is Sevelamer carbonate Zentiva approved?

Studies show that Sevelamer carbonate Zentiva is effective at reducing levels of blood phosphate in patients with hyperphosphataemia, and its side effects are considered manageable. The European Medicines Agency therefore decided that Sevelamer carbonate Zentiva's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Sevelamer carbonate Zentiva?

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

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

Other information about Sevelamer carbonate Zentiva

Sevelamer carbonate Zentiva received a marketing authorisation valid throughout the EU on 15 January 2015. This authorisation was based on the authorisation granted to Renvela in 2009 ('informed consent').

Further information on Sevelamer carbonate Zentiva 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 08-2018.