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Renvela (*sevelamer carbonate*)

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

What is Renvela and what is it used for?

Renvela 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.

Renvela 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 Renvela used?

Renvela is available as tablets (800 mg) and as powder (0.8 g, 1.6 g and 2.4 g) in a sachet to be taken 3 times a day with meals.

The dose to take depends on the patient's level of blood phosphate and, in case of children, their height and weight. Renvela 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 Renvela, see the package leaflet or contact your doctor or pharmacist.

How does Renvela work?

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

What benefits of Renvela have been shown in studies?

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

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In two main studies in 110 adults with kidney disease who were on dialysis, Renvela 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 authorised medicine Renagel.

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

Finally, a main study also showed that Renvela was effective at lowering phosphate levels in 100 children: children who took Renvela 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 Renvela?

The most common side effects with Renvela (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 with Renvela, see the package leaflet.

Renvela 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 Renvela authorised in the EU?

Studies show that Renvela is effective at reducing levels of blood phosphate in patients with hyperphosphataemia, and its side effects are considered manageable. The European Medicines Agency therefore concluded that Renvela'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 Renvela?

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

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

Other information about Renvela

Renvela received a marketing authorisation valid throughout the EU on 10 June 2009.

Further information on Renvela can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/renvela.

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