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EPAR summary for the public

Pantecta Control

pantoprazole

This is a summary of the European public assessment report (EPAR) for Pantecta Control. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Pantecta Control.

What is Pantecta Control?

Pantecta Control is a medicine that contains the active substance pantoprazole. It is available as gastroresistant tablets (20 mg). 'Gastroresistant' means that the tablet's contents pass through the stomach without being broken down until they reach the intestine. This prevents the active substance from being destroyed by the acid in the stomach.

Pantecta Control is similar to a 'reference medicine' already authorised in the European Union (EU) called Pantecta.

What is Pantecta Control used for?

Pantecta Control is used for the short-term treatment of the symptoms of acid reflux in adults. Acid reflux is when acid produced in the stomach escapes into the gullet, causing heartburn and acid regurgitation (acid flowing up into the mouth).

The medicine can be obtained without a prescription.

How is Pantecta Control used?

The recommended dose of Pantecta Control is one tablet once a day until symptoms have stopped. The patient may need to take the medicine for two to three days in a row for symptoms to improve. If there is no improvement in symptoms within two weeks of continuous treatment, patients should

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consult their doctor. Patients should not take the medicine for longer than four weeks without consulting their doctor.

The tablets should be swallowed whole with liquid before a meal and should not be chewed or crushed.

How does Pantecta Control work?

The active substance in Pantecta Control, pantoprazole, is a proton pump inhibitor. It works by blocking 'proton pumps', proteins found in specialised cells in the stomach lining that pump acid into the stomach. By blocking the pumps, pantoprazole reduces acid production, relieving the symptoms of acid reflux.

Pantoprazole-containing medicines have been available in the European Union (EU) since 1994. The reference medicine, Pantecta, is only available with a prescription. It is used for long-term treatments and is also used to treat a wider range of gastrointestinal diseases (conditions affecting the gut) than Pantecta Control.

How has Pantecta Control been studied?

Because pantoprazole has been in use for many years, the applicant presented data from the scientific literature. The applicant also presented information from two main studies looking at the effects of pantoprazole 20 mg in a total of 563 adults who had symptoms of acid reflux, including at least one episode of heartburn in the three days before the studies began. The first study compared pantoprazole with placebo (a dummy treatment) in 219 adults, and the second compared it with ranitidine (another medicine used to treat acid reflux symptoms) in 344 adults. The main measure of effectiveness was the number of patients with symptoms of heartburn over the first two weeks of treatment.

What benefit has Pantecta Control shown during the studies?

Pantoprazole was more effective than placebo and ranitidine at improving the symptoms of acid reflux. In the first study, 74% of the patients taking pantoprazole (80 out of 108) and 43% of those taking placebo (48 out of 111) had no heartburn after two weeks. Pantoprazole was also more effective than placebo at reducing symptoms of acid regurgitation. In the second study, 70% of the patients taking pantoprazole (121 out of 172) and 59% of those talking ranitidine (102 out of 172) had no heartburn after two weeks of treatment.

What is the risk associated with Pantecta Control?

The most common side effects with Pantecta Control (seen in around 1 patient in 100) are diarrhoea and headache. For the full list of all side effects reported with pantoprazole, see the package leaflet.

Pantecta Control must not be used in people who are hypersensitive (allergic) to pantoprazole, soya or any of the other ingredients. It must not be used with atazanavir (a medicine used to treat human immunodeficiency virus [HIV] infection).

Why has Pantecta Control been approved?

The CHMP noted that pantoprazole 20 mg was effective in the short-term treatment of reflux symptoms and that there is a long safety experience with the medicine as a prescription medicine. It was also of the opinion that, based on the experience of the use of pantoprazole, the availability of

Pantecta Control without medical supervision is appropriate. The CHMP therefore decided that Pantecta Control's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Pantecta Control

The European Commission granted a marketing authorisation valid throughout the EU for Pantecta Control on 12 June 2009.

The full EPAR for Pantecta Control 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 Pantecta Control, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 03-2013.