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EPAR summary for the public

Nexium Control

esomeprazole

This is a summary of the European public assessment report (EPAR) for Nexium Control. 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 Nexium Control.

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

What is Nexium Control and what is it used for?

Nexium Control is a medicine that contains the active substance esomeprazole. It is used in adults for the short-term treatment of reflux symptoms (sometimes called acid reflux), such as heartburn and acid regurgitation.

Nexium Control is similar to a 'reference medicine' already authorized in the European Union (EU) containing the same active substance, called Nexium. The reference medicine is only available with a prescription, but Nexium Control is intended for short term use without a prescription.

How is Nexium Control used?

Nexium Control can be obtained without a prescription. It is available as tablets (20 mg) which are gastro-resistant (the contents pass through the stomach without being broken down until they reach the intestine). The recommended dose is one tablet per day for up to 2 weeks until the symptoms are relieved. If symptoms persist after 2 weeks, the patient should see a doctor. For further information, see the package leaflet.

How does Nexium Control work?

The active substance in Nexium Control, esomeprazole, is a proton pump inhibitor. It works by blocking 'proton pumps', proteins found in specialised cells in the stomach lining, which pump acid into

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the stomach. By blocking the pumps, esomeprazole reduces acid production, thereby relieving the symptoms of acid reflux.

What benefits of Nexium Control have been shown in studies?

Nexium Control has been compared with placebo (a dummy treatment) in two main studies involving 718 adult patients with reflux symptoms including heartburn. The patients were treated for 4 weeks. The main measure of effectiveness in both studies was the percentage of patients whose heartburn symptoms had completely cleared up at the end of the study.

In the first study, around 34% of patients taking a 20 mg dose of Nexium Control (41 out of 121) had no more heartburn symptoms, compared with around 14% of patients taking placebo (17 out of 124). In the second study, around 42% of patients taking Nexium Control (47 out of 113) had no more heartburn symptoms, compared with around 12% of patients taking placebo (14 out of 118). In both studies, most patients whose symptoms completely cleared up had already achieved this in the first 2 weeks, while patients whose symptoms did not completely clear up in 2 weeks showed little further improvement from continued treatment.

What are the risks associated with Nexium Control?

Headache, abdominal pain, diarrhoea and nausea are among the most common side effects with Nexium Control (which may affect up to 1 in 10 patients). For the full list of all side effects reported with Nexium Control, see the package leaflet.

Nexium Control must not be used together with another medicine called nelfinavir (used to treat HIV infection). For the full list of restrictions, see the package leaflet.

Why is Nexium Control approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Nexium Control's benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP concluded that the medicine's effects were already well established, as esomeprazole-containing medicines have been authorised in EU countries since 2000, and that its short-term benefits had been demonstrated in studies where most patients' symptoms cleared up in 2 weeks. The Committee concluded that patients could safely treat themselves with the medicine for up to 2 weeks.

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

A risk management plan has been developed to ensure that Nexium Control 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 Nexium Control, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Nexium Control

The European Commission granted a marketing authorisation valid throughout the European Union for Nexium Control on 26 August 2013.

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

This summary was last updated in 08-2013.