27 June 2013
EMA/328140/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Nexium Control

esomeprazole

On 27 June 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Nexium Control, 20 mg, gastro-resistant tablet intended for the short-term treatment of reflux symptoms (e.g. heartburn and acid regurgitation) in adults. This medicinal product is to be made available as a non-prescription medicine.

The applicant for this medicinal product is AstraZeneca AB. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Nexium Control is esomeprazole, a proton pump inhibitor (A02BC05) and inhibits specifically the gastric H+/K+-ATPase enzyme, which is responsible for acid secretion in the parietal cells of the stomach.

The benefits with Nexium Control are its ability to relieve gastroesophageal reflux symptoms (e.g. heartburn and acid regurgitation). The most common side effects are headache and gastrointestinal disorders, i.e., abdominal pain, diarrhoea, flatulence, nausea/vomiting and constipation.

A pharmacovigilance plan for Nexium Control will be implemented as part of the marketing authorisation.

The approved indication is: “Nexium Control is indicated for the short-term treatment of reflux symptoms (e.g. heartburn and acid regurgitation) in adults.".

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Nexium Control and therefore recommends the granting of the marketing authorisation.