European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 19 February 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
CONTROLOC CONTROL

International Nonproprietary Name (INN): ***pantoprazole***

On 19 February 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Controloc Control 20 mg gastro-resistant tablet intended for short-term treatment of reflux symptoms (e.g. heartburn, acid regurgitation) in adults, as a medicinal product not subject to medical prescription. The applicant for this medicinal product is Nycomed GmbH.

The active substance of Controloc Control is pantoprazole, a proton pump inhibitor (ATC Code: A02BC02). It acts by inhibiting the secretion of hydrochloric acid in the stomach by specific blockade of the proton pumps of the parietal cells.

The benefits with Controloc Control are its ability to provide an effective short-term treatment in mild reflux symptoms associated with gastro-oesophageal reflux disease (GORD). Results of 17 randomized controlled clinical studies, in which 20 mg pantoprazole was investigated with regard to relief of reflux symptoms as a primary or secondary endpoint, have been presented. In these studies Controloc Control was shown to be significantly superior to placebo and H2-receptor antagonists, and statistically non-inferior to other proton-pump inhibitors in the complete relief from heartburn after 1 and 2 weeks. The most common side effects are diarrhoea and headache. Overall, the safety profile of pantoprazole is considered established on the basis of data from clinical studies as well as the worldwide post-marketing patient exposure. In general, initiation of treatment of GORD is based on symptoms. Based on the available data it is considered that Controloc Control in the sought indication is appropriate to be used as medicinal product not subject to medical prescription.

The approved indication is: “Short-term treatment of reflux symptoms (e.g. heartburn, acid regurgitation) in adults.” The legal status is: “Medicinal product not subject to medical prescription.”

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

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

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* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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