

Press Release

Positive CHMP opinion for Pantoprazole 20mg OTC will give pharmacists first line treatment for heartburn symptoms

Nycomed's PANTOZOL Control[®] (Pantoprazole 20mg) received a positive opinion from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP), recommending the granting of a marketing authorisation for PANTOZOL Control[®]. PANTOZOL Control[®] is intended for short-term treatment of reflux symptoms (e.g. heartburn, acid regurgitation) in adults as a medicinal product not subject to medical prescription.

Pantoprazole, the active ingredient of PANTOZOL Control[®], is a well-established therapy for acid-related gastrointestinal diseases that has been used by over 750 million patients. Pantoprazole belongs to the class of proton-pump-inhibitors (PPI), which are considered today as first line treatment for repeated heartburn and reflux disease by Gastroenterologists, and are widely prescribed. While classical antacids neutralise the hyperacidity in the stomach, PPIs act directly at the source, the proton-pump, which results in complete relief of symptoms for significantly more patients.

In its opinion on PANTOZOL Control[®], the CHMP concluded the benefit to risk balance to be favourable. Clinical data showed that PANTOZOL Control[®] is significantly superior to H₂-receptor antagonists.

"We believe that with PANTOZOL Control[®] pharmacists will have at their disposal a first line treatment that they can recommend to frequent heartburn sufferers with great confidence," said Etienne de Laroulière, Head of OTC at Nycomed. "When approved, pharmacists will have a very efficient drug to issue without mandatory medical prescription to heartburn patients," he continued.

PANTOZOL Control[®] is the first proton-pump-inhibitor recommended for European wide OTC marketing authorisation. It is the second OTC product to receive a positive CHMP opinion in the newly established centralised procedure for OTC. Marketing authorisation is expected for later this year.

The complete summary of the positive CHMP opinion can be downloaded at the EMA website: http://www.emea.europa.eu/pdfs/human/opinion/PantozolControl_2349409en.pdf

About Nycomed

Nycomed is a privately owned global pharmaceutical company with a differentiated portfolio focused on branded medicines in gastroenterology, respiratory and inflammatory diseases, pain, osteoporosis and tissue management. An extensive range of OTC products completes the portfolio.

Its R&D is built to be open for partnerships as in-licensing is a cornerstone in the company's growth strategy.

The company employs 12,000 associates worldwide, and its products are available in more than 100 countries. It has strong platforms in Europe and in fast-growing markets such as Russia/CIS, and Latin America. While the US and Japan are commercialised through best-in-class partners, Nycomed will further strengthen its position in key Asian markets.

Headquartered in Zurich/Switzerland, the company generated in 2007 total sales of € 3,5 billion and an adjusted EBITDA of € 1,2 billion.

For more information visit www.nycomed.com

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