

Press Release

Nycomed receives Marketing Authorization for Pantoprazole 20mg OTC from European Commission following unanimous vote of 27 EU member states

Nycomed received marketing authorisation from the European Commission for five applications: PANTOZOL Control[®], PANTOLOC Control[®], PANTECTA Control[®], SOMAC Control[®] and CONTROLOC Control[®].

This new OTC medication 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 traditional antacids neutralise the acid in the stomach, PPIs act directly at the source, the proton-pump, which results in sustainable relief of symptoms for sufferers.

Robust clinical evidence collected over the last 15 years demonstrates the safety of Pantoprazole. The same data shows Pantoprazole to be significantly efficacious in terms of providing sustainable relief of symptoms.

“We are looking forward to offer this OTC medication for the treatment of heartburn and in particular to frequent heartburn sufferers in the EU,” said Etienne de Laroullière, Head of OTC, Nycomed. “Pharmacists will now have at their disposal a very efficient drug to be recommended with great confidence to heartburn sufferers,” he added.

PANTOZOL Control[®] is the first proton-pump-inhibitor that received European wide OTC marketing authorisation. It is the second OTC product that received approval in the newly established centralised procedure for OTC.

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 inlicensing is a cornerstone of the company's growth strategy.

Nycomed 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 2008 total sales of €3,4 billion and an adjusted EBITDA of €1,2 billion.

For more information visit www.nycomed.com

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