11 November 2016
EMEA/H/C/001099

Public statement

Pantecta Control

Withdrawal of the marketing authorisation in the European Union

On 19 September 2016, the European Commission withdrew the marketing authorisation for Pantecta Control (pantoprazole) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Takeda GmbH, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Pantecta Control was granted marketing authorisation in the EU as an over-the-counter product on 12 June 2009 for the treatment of reflux symptoms (e.g. heartburn, acid regurgitation). The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2014.

Pantecta Control was a duplicate application to Pantozol Control 20 mg gastro-resistant tablets, which is marketed in several EU countries.

The marketing authorisation holder will maintain the marketing authorisation for Pantozol Control 20 mg gastro-resistant tablets and the remaining duplicates Controloc Control 20 mg gastro-resistant tablets, Somac Control 20 mg gastro-resistant tablets and Pantoloc Control 20 mg gastro-resistant tablets.

The European Public Assessment Report (EPAR) for Pantecta Control will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

An agency of the European Union