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Public statement

Pantoloc Control

Withdrawal of the marketing authorisation in the European Union

On 20 December 2021, the European Commission withdrew the marketing authorisation for Pantoloc 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.

Pantoloc Control was granted marketing authorisation in the EU on 12 June 2009 for 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. The product had not been marketed in the EU since 2019.

Pantoloc Control was a duplicate application to Somac Control, Controloc Control, Pantecta Control and Pantozol Control, which are marketed in several EU countries. The marketing authorisation holder will maintain the marketing authorisation for Somac Control, Controloc Control, Pantecta Control and Pantozol Control.

The European Public Assessment Report (EPAR) for Pantoloc Control will be updated to indicate that the marketing authorisation is no longer valid.

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