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Public statement

Clopidogrel DURA

Withdrawal of the marketing authorisation in the European Union

On 5 May 2015, the European Commission withdrew the marketing authorisation for Clopidogrel DURA (clopidogrel) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Mylan Dura GmbH, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Clopidogrel DURA was granted marketing authorisation in the EU on 27 July 2009 for the following indication:

Prevention of atherothrombotic events

Clopidogrel is indicated in:

• *Adults patients suffering from myocardial infarction (from a few days until less than 35 days), ischaemic stroke (from 7 days until less than 6 months) or established peripheral arterial disease.*

The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2014.

Clopidogrel DURA is a generic medicine of Plavix. There are other generic medicinal products of Plavix authorised and marketed in the EU.

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Report (EPAR) for Clopidogrel DURA will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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