20 December 2018
EMA/875585/2018
EMEA/H/C/004217

Public statement

Ivabradine JensonR

Withdrawal of the marketing authorisation in the European Union

On 6 December 2018, the European Commission withdrew the marketing authorisation for Ivabradine JensonR (ivabradine) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, JensonR+ Limited, which notified the European Commission of its decision not to market the product in the EU for commercial reasons.

Ivabradine JensonR was granted marketing authorisation in the EU on 11 November 2016 for the treatment of angina pectoris and chronic heart failure. The marketing authorisation was initially valid for 5 years. The product had not been marketed in the EU since the marketing authorisation was granted.

Ivabradine JensonR is a generic medicine of ivabradine. Other generic medicinal products of ivabradine are authorised and marketed in the EU.

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(EPAR) for Ivabradine JensonR will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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