22 March 2018
EMA/CHMP/171802/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Ivemend

fosaprepitant

On 22 March 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Ivemend. The marketing authorisation holder for this medicinal product is Merck Sharp & Dohme Limited.

The CHMP adopted an extension to the existing indication as follows [2]:

"~~Prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy in adults.~~

~~Prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy in adults~~

Prevention of nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in adults and paediatric patients aged 6 months and older.

IVEMEND 150 mg is given as part of a combination therapy."

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

[2] New text in bold, removed text as strikethrough

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