22 October 2015
EMA/CHMP/697606/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

EMEND

aprepitant

On 22 October 2015 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending changes to the terms of the marketing authorisation for the medicinal product EMEND. The marketing authorisation holder for this medicinal product is Merck Sharp & Dohme Limited.

The CHMP recommended approval of a new pharmaceutical form (125 mg powder for oral suspension) with a new indication as follows:

Prevention of nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in children, toddlers and infants from the age of 6 months to less than 12 years.

EMEND powder for oral suspension is given as part of combination therapy (see section 4.2).

Furthermore the CHMP adopted an extension to the existing indication for the 80mg and 125mg hard capsules as follows[2]:

Prevention of nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in adults and adolescents from the age of 12.

~~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.~~

EMEND 80 / 125 mg is given as part of combination therapy (see section 4.2).

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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