EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 April 2015
EMA/CHMP/245423/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Invega

paliperidone

On 23 April 2015, 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 Invega. The marketing authorisation holder for this medicinal product is Janssen-Cilag International N.V.

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

Invega is indicated for the treatment ~~of psychotic or manic symptoms~~ of schizoaffective disorder in adults. ~~Effect on depressive symptoms has not been demonstrated.~~

For information, the full indications for Invega will be as follows:

Invega is indicated for the treatment of schizophrenia in adults and in adolescents 15 years and older.

Invega is indicated for the treatment of schizoaffective disorder in adults.

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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