23 October 2014
EMA/CHMP/605917/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Paliperidone Janssen

paliperidone

On 23 October 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation based on an informed consent application for the medicinal product Paliperidone Janssen (25 mg, 50 mg, 100 mg, 150 mg, 150mg/100mg, prolonged-release suspension for injection). Paliperidone Janssen is intended for treatment of schizophrenia. The applicant for this medicinal product is Janssen-Cilag International NV.

The active substance of Paliperidone Janssen is paliperidone, a psycholeptic antipsychotic (N05 AX13). Paliperidone palmitate is a pro-drug of paliperidone, an active breakdown product (metabolite) of risperidone, another antipsychotic medicine that has been used in the treatment of schizophrenia since the 1990s. Based on its receptor pharmacology, the efficacy of paliperidone is mediated through a combined antagonist activity at D2 and 5-HT2A receptors.

The benefits with Paliperidone Janssen are its ability to reduce symptoms of schizophrenia and prevent the occurrence of new symptoms of schizophrenia in long term use.

The approved indication is:

“Paliperidone Janssen is indicated for maintenance treatment of schizophrenia in adult patients stabilised with paliperidone or risperidone. In selected adult patients with schizophrenia and previous responsiveness to oral paliperidone or risperidone, Paliperidone Janssen may be used without prior stabilisation with oral treatment if psychotic symptoms are mild to moderate and a long-acting injectable treatment is needed.”

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR)

[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.

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and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Paliperidone Janssen and therefore recommends the granting of the marketing authorisation.