30 April 2020
EMA/CHMP/230829/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Paliperidone Janssen-Cilag International

paliperidone

On 30 April 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Paliperidone Janssen-Cilag International, intended for the treatment of schizophrenia. The applicant for this medicinal product is Janssen-Cilag International N.V.

Paliperidone Janssen-Cilag International will be available as prolonged-release suspension for injection (25, 50, 75, 100 or 150 mg). The active substance of Paliperidone Janssen-Cilag International is paliperidone, a psycholeptic antipsychotic (ATC code: N05AX13). Paliperidone is an active breakdown product (metabolite) of risperidone, another antipsychotic medicine that has been used in the treatment of schizophrenia since the 1990s. Paliperidone's activity is mediated through a combination antagonist activity at D2 and 5-HT2A receptors.

The benefits of Paliperidone Janssen-Cilag International are its ability to reduce symptoms of schizophrenia (measured on a standard scale) and prevent new symptoms of schizophrenia with long-term use. The most common side effects (seen in more than 1 patient in 10) are insomnia, headache, anxiety, upper respiratory tract infection, injection site reactions, parkinsonism, increased weight, akathisia, agitation, sedation/somnolence, nausea, constipation, dizziness, musculoskeletal pain, tachycardia, tremor, abdominal pain, vomiting, diarrhoea, fatigue, and dystonia.

The application for Paliperidone Janssen-Cilag International was an informed consent application. In an informed consent application, reference is made to an authorised medicine where the marketing authorisation holder of the reference medicine has given consent to the use of their dossier in the application procedure. The reference product for Paliperidone Janssen-Cilag International is Xeplion.

The full indication is:

> 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-Cilag International may be used without prior stabilisation with oral treatment if psychotic symptoms are mild to moderate and a long-acting injectable treatment is needed.

[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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It is proposed that Paliperidone Janssen-Cilag International be prescribed by physicians experienced in the treatment of schizophrenia.

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