16 December 2010
EMA/777632/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Xeplion

paliperidone palmitate

On 16 December 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Xeplion, 25, 50, 75, 100 and 150 mg, prolonged release suspension for injection intended for treatment of schizophrenia. The applicant for this medicinal product is Janssen-Cilag International NV. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Xeplion is paliperidone palmitate, 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 combination antagonist activity at D2 and 5-HT2A receptors.

The benefits with Xeplion are its ability to reduce symptoms using a standard scale for schizophrenia and prevent the occurrence of new symptoms of schizophrenia in long term use.

The most common side effects (seen in more than 1 patient in 10) are insomnia (difficulty sleeping) and headache. Other common side effects (seen in between 1 and 10 patients in 100) are injection site pain or other reactions (such as swelling at the injection site), upper respiratory tract infection (infection of the nose, throat, or chest), parkinsonism (slow movements, tremor), akathisia (restlessness), dyskinesia (involuntary muscle contractions), dystonia (slow or sustained muscle contractions), weight gain, high blood sugar and triglycerides (fat), agitation, somnolence, dizziness, tachycardia (rapid heart rate), hypertension (high blood pressure), vomiting, upper abdominal pain, stomach discomfort, diarrhoea, nausea, constipation, toothache, rash, back pain, pain in the extremity and asthenia (tiredness).

The approved indication is:

[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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“Xeplion 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, Xeplion 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), and will be 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 Xeplion and therefore recommends the granting of the marketing authorisation.