25 January 2024
EMA/CHMP/18799/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Niapelf

paliperidone

On 25 January 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Niapelf, intended for the treatment of schizophrenia. The applicant for this medicinal product is Neuraxpharm Pharmaceuticals S.L.

Niapelf will be available as 25 mg, 50 mg, 75 mg, 100 mg, 150 mg + 100 mg and 150 mg prolonged-release suspension for injection. The active substance of Niapelf is paliperidone, a psycholeptic antipsychotic (ATC code: N05AX13). Paliperidone is the primary active metabolite of risperidone, which has been used in the treatment of schizophrenia since the 1990s. Paliperidone's therapeutic effect is mediated through antagonist activity at D2- and 5-HT2A receptors.

Niapelf is a generic of Xeplion, which has been authorised in the EU since 4 March 2011. Studies have demonstrated the satisfactory quality of Niapelf, and its bioequivalence to the reference product Xeplion. A question and answer document on generic medicines can be found here.

The full indication is:

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

Niapelf should 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.

[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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