16 December 2021
EMA/CHMP/726160/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Okedi

risperidone

On 16 December 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Okedi, intended for the treatment of schizophrenia in adults for whom tolerability and effectiveness has been established with oral risperidone.

The applicant for this medicinal product is Laboratorios Farmacéuticos Rovi, S.A.

Okedi will be available as 75 mg and 100 mg powder and solvent for prolonged-release suspension for injection. The active substance of Okedi is risperidone, a psycholeptic antipsychotic (N05 AX13). The effect of risperidone is mediated through a combined antagonist activity at the D2 and 5-HT2A receptors, which helps to regulate neurotransmitter activity in patients with schizophrenia.

Okedi is a hybrid medicine of Risperdal, which has been authorised in the EU since December 1993. Okedi contains the same active substance as Risperdal, but is a new injectable long-acting formulation containing risperidone in *in situ* microparticles (ISM). Studies have demonstrated the satisfactory quality of Okedi, and its bioequivalence to the reference product Risperdal.

The benefits of Okedi are its ability to reduce symptoms using a standard scale for schizophrenia and prevent the occurrence of new symptoms of schizophrenia with long-term use. It is also expected to improve patient adherence to treatment. The most frequently reported adverse events for Okedi are central nervous system disorders, psychiatric disorders, and gastrointestinal disorders. Other frequently reported adverse drug reactions of risperidone prolonged-release suspensions for intramuscular injection are insomnia, anxiety, headache, upper respiratory tract infection, parkinsonism, depression, and akathisia.

The full indication is:

> Treatment of schizophrenia in adults for whom tolerability and effectiveness has been established with oral risperidone.

[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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Okedi 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.