31 May 2018
EMA/344772/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Rxulti

brexpiprazole

On 31 May 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Rxulti, intended for the treatment of schizophrenia. The applicant for this medicinal product is Otsuka Pharmaceutical Europe Ltd.

Rxulti will be available as film-coated tablets (0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg and 4 mg). The active substance of Rxulti is brexpiprazole, an antipsychotic that binds primarily to dopamine D2 receptors, serotonin 5-HT1A and 5-HT2A receptors and noradrenergic α1B/2C receptors (ATC code: N05AX16).

The benefits with Rxulti are its ability to improve psychotic symptoms. The most common side effects are akathisia and weight gain.

The full indication is: "Rxulti is indicated for the treatment of schizophrenia in adult patients".

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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