18 May 2017
EMA/309096/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Reagila

cariprazine

On 18 May 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Reagila, intended for the treatment of schizophrenia. The applicant for this medicinal product is Gedeon Richter.

Reagila will be available as 1.5 mg, 3 mg, 4.5 mg and 6 mg hard capsules. The active substance of Reagila is cariprazine, an antipsychotic (ATC code: N05AX15). Cariprazine binds primarily to dopamine D3 and D2 receptors and serotonin 5-HT1A receptors.

The benefits with Reagila are its ability to improve psychotic symptoms. The most common side effects are akathisia and parkinsonism.

The full indication is: "Reagila 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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