24 October 2013
EMA/CHMP/630715/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Brintellix

vortioxetine

On 24 October 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Brintellix, 5mg, 10mg, 15mg, 20mg, film-coated tablet and 20mg/ml oral drops (solution) intended for the treatment of major depressive episodes in adults. The applicant for this medicinal product is H. Lundbeck A/S. 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 Brintellix is vortioxetine, an antidepressant (ATC Code N06AX26), and its mechanism of action is thought to be related to its direct modulation of serotonergic receptor activity and inhibition of the serotonin (5-HT) transporter.

The benefits with Brintellix are based on its ability to reduce a broad range of depressive symptoms.
The most common side effect is nausea.

A pharmacovigilance plan for Brintellix will be implemented as part of the marketing authorisation.

The approved indication is “treatment of major depressive episodes in adults”. It is proposed that Brintellix is subject to medical prescription.

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.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Brintellix and therefore recommends the granting of the marketing authorisation.

[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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