19 June 2025
EMA/CHMP/170298/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Austedo

deutetrabenazine

On 19 June 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Austedo, intended for the treatment of adults with moderate to severe tardive dyskinesia. The applicant for this medicinal product is TEVA GmbH.

Austedo will be available as 12 mg, 24 mg, 30 mg, 36 mg, 42 mg and 48 mg prolonged-release tablets.

The active substance of Austedo is deutetrabenazine, a nervous system drug (ATC code: N07XX16). Deutetrabenazine is a reversible inhibitor of the vesicular monoamine transporter 2 (VMAT2). By inhibiting VMAT2, deutetrabenazine reduces the uptake of monoamines (such as dopamine, serotonin, norepinephrine, and histamine) into synaptic vesicles, leading to depletion of monoamine stores in dopaminergic regions of the brain (e.g. striatum and cortex). Although the precise mechanism of action of deutetrabenazine for the treatment of tardive dyskinesia is unknown, it is thought to relate to its ability to deplete monoamines from nerve terminals.

The benefit of Austedo is an improvement in the severity of abnormal involuntary movements, assessed by the Abnormal Involuntary Movement Scale (AIMS), after 12 weeks of treatment compared with placebo, as shown in two randomised, double-blind, placebo-controlled trials. The most common side effects with Austedo include somnolence, diarrhoea, dry mouth and fatigue.

The full indication is:

> Austedo is indicated for the treatment of moderate to severe tardive dyskinesia in adults.

The initiation and titration of Austedo treatment should be supervised by a physician with experience in drug-induced movement disorders.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website 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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