EMA/218064/2025
EMEA/H/C/006371

Austedo (*deutetrabenazine*)

An overview of Austedo and why it is authorised in the EU

What is Austedo and what is it used for?

Austedo is a medicine used in adults to treat moderate to severe tardive dyskinesia, a condition where the face, body or both make sudden, irregular movements that cannot be controlled. Tardive dyskinesia usually develops as a side effect of certain medicines.

Austedo contains the active substance deutetrabenazine.

How is Austedo used?

Austedo can only be obtained with a prescription. Treatment with Austedo should be started and adjusted under the supervision of a doctor experienced in treating movement disorders that occur as a side effect of medicines.

Austedo is available as a prolonged-release tablet that is taken by mouth once daily. Prolonged-release means that the active substance is released slowly over an extended period. The dose of Austedo is gradually increased each week, depending on how well the symptoms of tardive dyskinesia improve and whether the patient develops any side effects, until a suitable maintenance dose is reached.

Treatment can be continued for as long as the patient benefits from it and does not develop serious side effects.

For more information about using Austedo, see the package leaflet or contact your doctor or pharmacist.

How does Austedo work?

The active substance in Austedo, deutetrabenazine, works by blocking a protein in the brain called VMAT2. This protein helps store certain neurotransmitters (substances nerve cells use to communicate with other cells). This results in lower amounts of these neurotransmitters in certain parts of the brain, especially areas involved in controlling movement. Although the way in which deutetrabenazine works in the treatment of tardive dyskinesia is not fully understood, it is thought that by reducing levels of these neurotransmitters it helps to control the sudden, irregular movements associated with tardive dyskinesia.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

What benefits of Austedo have been shown in studies?

In two main studies, Austedo was more effective than placebo (a dummy treatment) in reducing the severity of involuntary movements in adults with tardive dyskinesia. In both studies the main measure of effectiveness was the change in Abnormal Involuntary Movement Scale (AIMS) after 12 weeks of treatment. The AIMS evaluates the severity of abnormal movements in the face (including mouth and tongue), limbs, and trunk, using a scale of 0 to 4. A lower score indicates less severe movements.

The first study involved 117 adults with tardive dyskinesia who received treatment with either Austedo or placebo. Everyone treated with Austedo started on a dose of 12 mg per day and gradually increased their dose over 6 weeks until they reached a suitable maintenance dose. They then continued treatment at that dose for another 6 weeks. Those given Austedo had an average reduction of 3 in their AIMS score compared with an average reduction of 1.6 for those given placebo.

The second study involved 298 adults with tardive dyskinesia who received treatment with either Austedo or placebo. Those given Austedo started treatment on one of three different doses and gradually increased their dose over 4 weeks until they reached a suitable maintenance dose. They then continued treatment with this dose for another 8 weeks. Patients who started treatment with Austedo on a dose of 12 mg had an average reduction of 2.1 in their AIMS score, those who started treatment on a dose of 24 mg had an average reduction of 3.2 in their AIMS score and those who started treatment on a dose of 36 mg had an average reduction of 3.3 in their AIMS score. In comparison, those given placebo had an average reduction of 1.4 in their AIMS score.

What are the risks associated with Austedo?

For the full list of side effects and restrictions with Austedo, see the package leaflet.

The most common side effects with Austedo include sleepiness (which may affect more than 1 in 10 people), as well as diarrhoea, dry mouth and tiredness (which may affect up to 1 in 10 people).

Some side effects can be serious. The most frequent (which may affect up to 1 in 10 people) include depression and dysthymic disorder (a mild, but long-lasting form of depression).

Austedo must not be used by people with liver problems, as well as those taking certain medicines. These medicines include reserpine (a medicine used to treat high blood pressure), other medicines that work in a similar way as deutetrabenazine and a class of medicines known as monoamine oxidase inhibitors (MAOIs).

Why is Austedo authorised in the EU?

There is an unmet need for new treatments for tardive dyskinesia that are both safe and effective, and that do not disrupt treatment for the underlying condition. Although there were some uncertainties with the main studies, such as the small number of patients involved and their short duration, Austedo was more effective than placebo at improving the severity of involuntary movements in adults with moderate to severe forms of tardive dyskinesia. Overall, the safety profile of Austedo was considered to be manageable.

The European Medicines Agency therefore decided that Austedo’s benefits are greater than its risks and that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Austedo?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Austedo have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Austedo are continuously monitored. Suspected side effects reported with Austedo are carefully evaluated and any necessary action taken to protect patients.

Other information about Austedo

Austedo received a marketing authorisation valid throughout the EU on 8 January 2026

Further information on Austedo can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/austedo.

This overview was last updated in 12-2025.