

**Patient leaflet in accordance with the Pharmacists' Regulations
(Preparations) - 1986**

This medicine is dispensed with a doctor's prescription only

Austedo 6 mg

**Extended-release
tablets**

Composition:

Each tablet contains:
Deutetrabenazine 6 mg

Austedo 9 mg

**Extended-release
tablets**

Composition:

Each tablet contains:
Deutetrabenazine 9 mg

Austedo 12 mg

**Extended-release
tablets**

Composition:

Each tablet contains:
Deutetrabenazine 12 mg

For information about inactive ingredients and allergens, see section 2 'Important information about some of this medicine's ingredients and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

- Austedo may cause serious side effects in people with Huntington's disease, including:
 - Depression
 - Suicidal thoughts
 - Suicidal actions
- Do not start taking Austedo if you have Huntington's disease and suffer from depression (have untreated depression or depression that is not well controlled by medicine) **or** have suicidal thoughts.
- Pay close attention to any changes, especially sudden changes in mood, behavior, thoughts or feelings. This is especially important when use of Austedo is started and when the dose is changed.

Contact your doctor immediately if you become depressed or have any of the following symptoms, especially if the symptom is new, worsening or worries you:

- You feel sad or have crying attacks.
- You lose interest in seeing your friends or doing things you used to enjoy.
- You sleep a lot more or a lot less than usual.
- You feel unimportant.
- You feel guilty.
- You feel hopeless or helpless.
- You feel more irritable, angry, or aggressive than usual.
- You feel more or less hungry than usual or notice a big change in your body weight.
- You have trouble concentrating.
- You feel tired or sleepy all the time.
- You have thoughts about hurting yourself or ending your life.

1. What is this medicine intended for?

Austedo is used in adults to treat:

- Chorea due to Huntington's disease.
- Tardive dyskinesia.

Therapeutic group: Medicines acting on the central nervous system.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 2 - "Important information about some of this medicine's ingredients" and section 6 - "Additional information").
- You have Huntington's disease and are depressed or have suicidal thoughts.
- You have liver problems.
- You are taking reserpine. **Do not** take medicines that contain reserpine with Austedo. If your doctor plans to switch your treatment from reserpine to Austedo, you must wait at least 20 days after your last dose of reserpine before you start treatment with Austedo.
- You are taking medicines of the monoamine oxidase inhibitors (MAOI) group. **Do not** take an MAOI within 14 days after you stop taking Austedo. **Do not** start taking Austedo if you stopped taking an MAOI in the last 14 days. Consult your doctor or pharmacist if you are not sure.
- You are taking tetrabenazine. If your doctor plans to switch your treatment from tetrabenazine to Austedo, take your first dose of Austedo on the day after your last dose of tetrabenazine.
- You are taking valbenazine.

Special warnings about using this medicine:

Before starting treatment with Austedo, tell your doctor if:

- You have emotional or mental problems (for example, depression, nervousness, anxiety, anger, agitation, psychosis, previous suicidal thoughts or suicide attempts).
- You have a liver disease.
- You have an irregular heart rhythm or heartbeat (QT prolongation, cardiac arrhythmia) or a heart problem called congenital prolonged QT syndrome.
- You have low levels of potassium or magnesium in your blood (hypokalemia or hypomagnesemia).
- You have breast cancer or a history of breast cancer.

Children and adolescents:

There is no information about the safety and efficacy of using this medicine in children and adolescents.

Drug interactions:

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- Medicines inhibiting activity of the enzyme called CYP2D6 (such as paroxetine, fluoxetine, quinidine and bupropion)
- Reserpine (a medicine used for treatment of high blood pressure).
- Antidepressants belonging to the group of drugs called monoamine oxidase inhibitors (MAOIs). See section 2 – 'Do not use this medicine if'.
- Neuroleptic medicines.
- Alcohol or sedatives, since combining them with Austedo may increase the sensation of sleepiness and sedation.
- Tetrabenazine and valbenazine.

Using this medicine and food:

Take the medicine with food.

Using this medicine and alcohol consumption:

Drinking alcohol and taking other drugs that may cause sleepiness while you are taking Austedo may increase the sleepiness caused by Austedo.

Pregnancy and breastfeeding:

If you are pregnant, breastfeeding, think that you are pregnant or are planning to become pregnant, consult your doctor before using this medicine.

It is not known if deutetrabenazine may harm a fetus or passes into breast milk.

Driving and using machines:

Sleepiness (sedation) is a common side effect during treatment with Austedo. Do not drive or operate dangerous machines during the treatment until you know how Austedo affects you.

Important information about some of this medicine's ingredients:

- Austedo 6 mg contains the red dye Allura Red AC, which may cause allergic reactions.
- Austedo 12 mg contains the yellow dye Sunset yellow FCF, which may cause allergic reactions.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions.

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.

The recommended starting dosage of Austedo is usually 6 mg twice daily (overall 12 mg per day). The dosage can be increased at weekly intervals by 6 mg per day, depending on reduction of chorea or tardive dyskinesia symptoms and tolerability of the medicine, up to a maximum recommended daily dosage of 48 mg.

Do not exceed the recommended dose.

Manner of administration:

- Take Austedo with food.
- Swallow Austedo tablets whole with water.
- If the daily dosage of Austedo is 12 mg per day or more, take the medicine twice a day in two equal doses.
- The doctor will increase the medicine dose each week for several weeks, until he finds the suitable dose for you.

Crushing/splitting/chewing:

- Do not chew, crush or break Austedo tablets before swallowing them, in order not to harm the extended release of the medicine in the body.
- If you cannot swallow Austedo tablets whole, consult your doctor or pharmacist. You may need another medicine.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. Symptoms of overdose may include acute dystonia, oculogyric crisis, nausea and vomiting, sweating, somnolence, low blood pressure, confusion, diarrhea, hallucinations, skin redness and tremor.

If you forget to take the medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult your doctor.

Adhere to the treatment as recommended by your doctor. Even if your health improves, do not stop taking this medicine without consulting your doctor.

If you stop taking the medicine for more than 1 week, tell your doctor. Do not take another dose until you consult your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Austedo may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Austedo may cause serious side effects, including:

- **Depression and suicidal thoughts or taking suicidal actions in people with Huntington's disease.**
- **Irregular heartbeat (QT prolongation).** Austedo increases the risk of certain changes in the electrical activity in your heart. These changes may lead to a

dangerously abnormal heartbeat. Taking Austedo with certain medicines may increase this risk.

- **Neuroleptic Malignant Syndrome (NMS).** Contact your doctor immediately and go to the emergency room immediately if you develop the following signs and symptoms with no obvious other cause:
 - High fever
 - Problems thinking
 - Increased sweating
 - Stiff muscles
 - Very fast or uneven heartbeat
- **Restlessness.** You may feel a strong and urgent need to move. This condition is called akathisia.
- **Parkinsonism.** Symptoms of parkinsonism include: slight shaking, body stiffness, trouble moving or keeping your balance, falls.
- **Sedation and sleepiness.**
- **High blood prolactin level.** This may be manifested by amenorrhea, secretion of milk from the breasts (galactorrhea) and breast enlargement in men (gynecomastia).
- **Binding to melanin-containing tissues.** The active ingredient deutetrabenazine or its metabolites bind to melanin-containing tissues and may accumulate in these tissues over time. Although there are no specific recommendations for periodic follow-up by an ophthalmologist, your doctor is aware of the possibility of long-term ophthalmological effects.

Most common side effects in people with Huntington's disease include:

- Sleepiness (sedation)
- Diarrhea
- Tiredness
- Dry mouth

Most common side effects in people with tardive dyskinesia include:

- Inflammation of the nose and throat (nasopharyngitis)
- Problems sleeping (insomnia)

Additional side effects:

in patients with Huntington's disease:

- Urinary tract infections
- Problems sleeping (insomnia)
- Anxiety
- Constipation
- Bruises

in patients with tardive dyskinesia:

- Depression/dysthymia
- Restlessness/akathisia

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects:

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:

<https://sideeffects.health.gov.il>

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions:

Store below 25°C and protect from light and moisture.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Mannitol, microcrystalline cellulose, polyethylene oxide, povidone, polysorbate 80, magnesium stearate, butylated hydroxyanisole, butylated hydroxytoluene, polyvinyl alcohol, titanium dioxide, macrogol, talc, FD&C blue #2 (Indigo Carmine), printing ink.

Austedo 6 mg also contains: FD&C red #40 lake (Allura Red AC).

Austedo 12 mg also contains: FD&C yellow #6 lake (Sunset Yellow FCF).

What the medicine looks like and contents of the pack:

Austedo 6 mg: round, purple-coated tablet, with "SD" over "6" printed in black ink on one side.

Austedo 9 mg: round, blue-coated tablet, with "SD" over "9" printed in black ink on one side.

Austedo 12 mg: round, beige-coated tablets, with "SD" over "12" printed in black ink on one side.

Each pack contains 60 tablets in a bottle.

Registration holder and manufacturer's name and address:

Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel Aviv 6944020.

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Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

Austedo 6 mg: 166.57.36154

Austedo 9 mg: 166.58.36155

Austedo 12 mg: 166.59.36156