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SKU (s): 32108197 - 32108199  
32108201 - 32108212  
32108215 - 32108189

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### Package leaflet: Information for the patient

## Austedo 12 mg, 24 mg, 30 mg, 36 mg, 42 mg and 48 mg Prolonged-release Tablets, treatment initiation pack

## Austedo 24 mg, 30 mg, 36 mg, 42 mg and 48 mg Prolonged-release Tablets

deutetrabenazine

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet

1. What Austedo is and what it is used for
2. What you need to know before you take Austedo
3. How to take Austedo
4. Possible side effects
5. How to store Austedo
6. Contents of the pack and other information

### 1. What Austedo is and what it is used for

Austedo is a medicine containing the active substance deutetrabenazine. It belongs to a group of medicines that treat disorders of the nervous system.

This medicine is used in adults to treat moderate to severe tardive dyskinesia. This is a condition that causes the face, tongue, or other body parts to make uncontrollable movements such as smacking of the lips, sticking out of the tongue and jerking or twisting of the arms and legs, and can develop with use of certain medicines.

Austedo decreases the uncontrollable movements associated with tardive dyskinesia by reducing the amount of dopamine, a messenger substance in the brain.

### 2. What you need to know before you take Austedo

#### Do not take Austedo if you:

- are allergic to deutetrabenazine or any of the other ingredients of this medicine (listed in section 6).
- have liver problems.
- are taking:
  - reserpine (a medicine used to treat high blood pressure)
  - a monoamine oxidase inhibitor (a medicine used to treat depression, Parkinson's disease or bacterial infections)
  - another medicine that works in a similar way to Austedo to reduce your uncontrollable movements.
 (see "Other medicines and Austedo", in this section).

If you are not sure, talk to your doctor or pharmacist before taking this medicine.

#### Warnings and precautions

Talk to your doctor or pharmacist **before** taking Austedo if you:

- have or have had depression
- have or have had an irregular heart rhythm
- have a family history of a heart condition known as congenital long QT syndrome (abnormal electrical activity of the heart that affects its rhythm)
- have a slow heart rate
- have low levels of potassium or magnesium, as seen in your blood tests.

Talk to your doctor immediately **while** taking Austedo if you:

- start feeling sad, worthless, hopeless or helpless or start losing interest in seeing your friends or doing things you used to enjoy (symptoms of a depression). If these symptoms do not get better, your doctor might consider stopping Austedo. You may find it helpful to ask a relative or close friend to tell your doctor immediately if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.
- start experiencing a rapid onset of shortness of breath, heart palpitations (sensation of rapid or irregular heartbeat) or loss of consciousness. These may be symptoms of a heart rhythm disorder known as QTc prolongation.
- start experiencing symptoms like high temperature, muscle stiffness, sweating, a lowered level of consciousness or very rapid or irregular heartbeat, low or high blood pressure. This is known as neuroleptic malignant syndrome, which can be life-threatening. Stop taking Austedo and talk to your doctor straight away. Your doctor will treat your symptoms.
- get a condition where you feel a constant urge to move (akathisia) or if you experience shaking, muscle stiffness and slow movement (parkinsonism). Your doctor may need to adjust your dose or stop your treatment.

Talk to your doctor if you notice new skin or eye problems. Deutetrabenazine binds to body tissues that contain melanin (a pigment that gives colour to skin and eyes). This may possibly affect these tissues if the medicine is used long-term.

#### Children and adolescents

There is no relevant use of Austedo in children and adolescents.

#### Other medicines and Austedo

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take this medicine if you are already taking:

- reserpine (a medicine used to treat high blood pressure). After your doctor has stopped reserpine you must wait at least 20 days after your last dose of reserpine before you can start taking Austedo.
- a monoamine oxidase inhibitor (MAOI) e.g.:
  - moclobemide, tranylcypromine and isocarboxazid (medicines used to treat depression)
  - selegiline, rasagiline and safinamide (medicines used to treat Parkinson's disease)
  - linezolid (medicine used to treat bacterial infections).

After your doctor has stopped the MAOI you must wait at least 14 days after your last dose of the MAOI before you can start taking Austedo.

- another medicine that works in a similar way to Austedo to reduce your uncontrollable movements (e.g. tetrabenazine). Your doctor will decide and tell you what to do.

Tell your doctor if you are taking, have recently taken or might take:

- medicines to treat
  - some mental or behavioural problems (e.g. psychosis such as haloperidol, chlorpromazine, ziprasidone, promazine)
  - nausea and vomiting (e.g. metoclopramide)

These medicines may increase the risk for symptoms such as shaking, muscle stiffness and slow movement (called parkinsonism), high temperature, muscle stiffness, low or high blood pressure and lowered level of consciousness (called neuroleptic malignant syndrome), or a constant urge to move (called akathisia).

- medicines that can influence your heart rhythm (visible on electrocardiogram) also known as QTc prolongation, for example, medicines used to treat
  - an irregular heart rhythm (e.g. quinidine, disopyramide, amiodarone, sotalol)
  - some mental or behavioural problems (e.g. phenothiazine derivatives, pimozide, haloperidol, droperidol, ziprasidone)
  - depression (e.g. amitriptyline, citalopram, escitalopram)
  - bacterial, fungal or other microbial infections (e.g. fluoroquinolones, triazole derivative (e.g. voriconazole), erythromycin IV, pentamidine, antimalarial medicines)
  - allergies (e.g. mizolastine, hydroxyzine)
- medicines that have a sedating effect, for example, medicines
  - to treat allergic conditions (e.g. diphenhydramine, dimenhydrinate)
  - to help you sleep or to calm down (e.g. midazolam, diazepam, lorazepam)
  - to treat severe pain (e.g. oxycodone, buprenorphine)
  - to treat high blood pressure (e.g. clonidine, moxonidine)
  - to treat depression (e.g. mirtazapine, amitriptyline, trazodone)
  - to treat some mental or behavioural problems (e.g. promethazine, chlorprothixene)

These medicines may increase the sedation and sleepiness which could be caused by Austedo.

- medicines to treat an irregular heart rhythm (e.g. quinidine) or depression (e.g. paroxetine, fluoxetine and bupropion). These medicines can interfere with the breakdown of deutetrabenazine. Your doctor may decrease your dose of Austedo.
- medicines to treat Parkinson's disease (e.g. levodopa) and medicines that work in a similar way like levodopa (e.g. also to treat Parkinson's disease and restless legs syndrome, e.g. pramipexole, ropinirole). These medicines may weaken the effect of Austedo.

#### Austedo with alcohol

It is not recommended to consume alcohol while you are being treated with Austedo, as it may increase the sedative effect and sleepiness that could be caused by this medicine.

#### Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Austedo is not recommended during pregnancy and in women of childbearing potential not using contraception.

It is not known if deutetrabenazine passes into breast milk. Thus, a risk for the breast-fed baby cannot be excluded. You should discuss with your doctor if you can take Austedo while breast-feeding.

### Driving and using machines

Austedo may cause sleepiness. Therefore, you should not perform activities requiring mental alertness, such as operating a motor vehicle or operating hazardous machinery, until you are on your maintenance dose of Austedo and you know how the medicine affects you.

### Information about some of the ingredients of Austedo

This medicine contains less than 1 mmol sodium (23 mg) per prolonged-release tablet, that is to say essentially 'sodium-free'.

### Austedo contains sunset yellow FCF and/or allura red AC (see section 6 "What Austedo contains")

This medicine may cause allergic reactions.

## 3. How to take Austedo

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will decide what dose is appropriate for you.

When you first start taking Austedo, you will be given a treatment initiation pack which your doctor will use to gradually increase your dose. Treatment starts at 12 mg once daily for one week. After that, the dose should be increased to 24 mg once daily for another week. Then, the dose can be adjusted weekly if needed, increasing by 6 mg each time, until you have reached a dose that effectively controls your symptoms and is well-tolerated. This becomes your maintenance dose (usually between 24 mg and 48 mg per day).

Consult your doctor if your symptoms worsen or side effects occur.

The prolonged-release tablets are for oral use and can be taken with or without food.

Tablets must be swallowed whole with water, not chewed, crushed or divided.

The tablet does not dissolve completely after all of the active substance has been released and sometimes the tablet shell may appear in your stool. This is normal.

### If you take more Austedo than you should

If you have taken more tablets than prescribed contact your doctor or nearest hospital straight away. You may experience symptoms such as sleepiness, increase in movements, tiredness, difficulty sitting and standing still (agitation), restlessness, difficulty falling and staying asleep, or suicidal thoughts or ideas.

### If you forget to take Austedo

If you have missed your daily dose for one day or several days in a row (but not for more than 7 days), continue taking your current dose the next day. Contact your doctor if there are any concerns or you are unsure what to do. Do not take a double dose to make up for a missed dose. If you have missed your daily dose for more than one week ask your doctor how your treatment should be restarted.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Please contact your doctor immediately** if you start feeling sad, worthless, hopeless or helpless or start losing interest in seeing your friends or doing things you used to enjoy. These are symptoms of a depression or dysthymic disorder, which may occur commonly (may affect up to 1 in 10 people).

**Very common** (may affect more than 1 in 10 people)

- sleepiness (somnolence).

**Common** (may affect up to 1 in 10 people)

- infection of the parts of the body that collect and pass out urine, such as the bladder (urinary tract infection)
- inflammation of the nose and throat (nasopharyngitis)
- feeling anxious
- difficulty sleeping (insomnia)
- difficulty standing or sitting still (agitation)
- restlessness
- constant urge to move (akathisia)
- diarrhoea
- constipation
- dry mouth
- tiredness (fatigue)
- bruising (contusion).

**Uncommon** (may affect up to 1 in 100 people)

- movement symptoms similar to Parkinson's disease such as shaking, muscle stiffness and slow movement (parkinsonism).

### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Austedo

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

### Austedo 12 mg, 24 mg, 30 mg, 36 mg, 42 mg, 48 mg Prolonged-release Tablets (treatment initiation pack)

Do not store above 30 °C.

### Austedo 24 mg, 30 mg, 36 mg, 42 mg and 48 mg Prolonged-release Tablets (maintenance packs)

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What Austedo contains

- The active substance is deutetrabenazine. Each prolonged release tablet contains either 12 mg, 24 mg, 30 mg, 36 mg, 42 mg or 48 mg deutetrabenazine.

- The other ingredients are

**Tablet:** butylhydroxyanisole (E 320), butylhydroxytoluene (E 321), macrogol high-molecular-mass 200K, macrogol high-molecular-mass 5000K, hypromellose 2910, sodium chloride, allura red AC (E 129), magnesium stearate, cellulose acetate, macrogol 3350, hydroxypropylcellulose.

**Film-coating:** poly(vinyl alcohol), titanium dioxide (E 171), macrogol 3350, talc

**Austedo 12 mg:**

indigo carmine (E 132)

**Austedo 24 mg:**

indigo carmine (E 132),

allura red AC (E 129)

**Austedo 30 mg:**

sunset yellow FCF (E 110)

**Austedo 36 mg:**

indigo carmine (E 132),

sunset yellow FCF (E 110),

allura red AC (E 129)

**Austedo 42 mg:**

sunset yellow FCF (E 110),

allura red AC (E 129)

**Austedo 48 mg:**

allura red AC (E 129).

See section 2 "Austedo contains sunset yellow FCF and/or allura red AC".

**Printing ink:**

shellac, iron oxide black (E 172), propylene glycol.

### What Austedo looks like and contents of the pack

Austedo 12 mg Prolonged-release Tablets are round, blue, film-coated, with a diameter of approximately 9 mm and "Q12" printed in black ink on one side.

Austedo 24 mg Prolonged-release Tablets are round, purple, film-coated, with a diameter of approximately 9 mm and "Q24" printed in black ink on one side.

Austedo 30 mg Prolonged-release Tablets are round, light orange, film-coated, with a diameter of approximately 10 mm and "Q30" printed in black ink on one side.

Austedo 36 mg Prolonged-release Tablets are round, light purple, film-coated, with a diameter of approximately 10 mm and "Q36" printed in black ink on one side.

Austedo 42 mg Prolonged-release Tablets are round, orange, film-coated, with a diameter of approximately 10 mm and "Q42" printed in black ink on one side.

Austedo 48 mg Prolonged-release Tablets are round, pink, film-coated, with a diameter of approximately 10 mm and "Q48" printed in black ink on one side.

### Treatment initiation pack

Austedo 12 mg, 24 mg, 30 mg, 36 mg, 42 mg, 48 mg is available in a pack of 42 prolonged-release tablets containing two wallet cards one with 21 (7 x 12 mg, 7 x 24 mg, 7 x 30 mg) and another one with 21 (7 x 36 mg, 7 x 42 mg, 7 x 48 mg) prolonged-release tablets.

### Maintenance packs

Austedo 24 mg, 30 mg, 36 mg, 42 mg, 48 mg are available in packs of 28 and 84 prolonged-release tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder: Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer: Teva Operations Poland Sp. z o.o., ul. Mogilska 80, Kraków, 31-546, Poland

### This leaflet was last revised in January 2026.

PL 00289/2637, PL 00289/2638, PL 00289/2639, PL 00289/2640, PL 00289/2641 and PL 00289/2642