

PACKAGE LEAFLET

Package leaflet: Information for the user

Tardiben 25 mg tablets

Tetrabenazine

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 Tardiben is and what it is used for
2. What you need to know before you take Tardiben
3. How to take Tardiben
4. Possible side effects
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1. What Tardiben is and what it is used for

Tardiben contains a substance called tetrabenazine. This is a medicine belonging to the group that treats disorders of the nervous system.

Tardiben is used for the treatment of diseases causing jerky, irregular, uncontrollable movements (hyperkinetic motor disorders with Huntington's chorea).

Tardiben is also indicated for the treatment of moderate to severe Tardive Dyskinesia:

- Tardive dyskinesia is a condition characterised by uncontrollable movements such as facial spasm, grimacing, or peculiar tongue movements.
- Some medicines used to treat certain mental health conditions (antipsychotics) can cause tardive dyskinesia.
- Tardiben should only be given to you for the treatment of tardive dyskinesia when symptoms are moderate to severe, disabling, and/or embarrassing in social situations.
- Tardiben should only be given to you when symptoms persist, even after your doctor has stopped, changed, or reduced the dose of your antipsychotic medication.

2. What you need to know before you take Tardiben

Do not take Tardiben:

- if you are allergic (hypersensitive) to tetrabenazine or any of the other ingredients of Tardiben (listed in section 6).
- if you use reserpine (medicine to control high blood pressure and to treat psychotic states).
- if you use MAO inhibitors (medicine to treat depression).
- if you suffer from Parkinson-like symptoms.
- if you have depression.
- if you have suicidal thoughts.
- if you are breast-feeding.
- if you suffer from pheochromocytoma (tumour of the adrenal gland).
- if you suffer from prolactin-dependent tumours, e.g. pituitary or breast cancer.

Warnings and precautions

Talk to your doctor or pharmacist before taking Tardiben.

- if you have liver problems.
- if you have ever had trembling in the hands and jerky movements in the arms and legs, known as parkinsonism.
- if you suffer from high blood concentrations of prolactin (Hyperprolactinemia).
- if you are vulnerable to sudden drop in blood pressure when standing up or stretching.
- if you know that you are a slow or intermediate metaboliser of an enzyme called CYP2D6, because a different dose may be applicable for you.
- if you have a heart condition known as long QT syndrome or if you have or have had problems with your heart rhythm.
- if you start to have mental changes such as confusion or hallucinations, or develop stiffness in your muscles and a temperature, you may be developing a condition called Neuroleptic Malignant Syndrome. If you have these symptoms please contact your doctor straight away.
- if you start to have neurological disorders such as muscular stiffness, unpleasant sensations of inner restlessness or agitation, a compelling need to be in constant motion, disturbances in arbitrary movement or involuntary movements. Contact your doctor if you experience a worsening of your motor abilities.
- please consider that tetrabenazine, the active substance of Tardiben, binds to melanin containing tissues (pigment of hairs, skin and eye) resulting in the possibility to cause toxicity in these tissues.

Children

Tardiben is not recommended in children.

Other medicines and Tardiben

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Take special care if you use Tardiben together with:

- levodopa (a medicine used to treat Parkinson's disease).
- drugs known to prolong the QTc interval including:
 - some drugs used to treat mental health conditions (e.g. chlorpromazine, thioridazine).
 - certain antibiotics (e.g. gatifloxacin, moxifloxacin).
 - some drugs used to treat problems with heart rhythm conditions (e.g. quinidine, procainamide, amiodarone, sotalol).
- opioids (pain killers).
- beta blockers and antihypertensive drugs (medicines to treat high blood pressure).
- hypnotics and neuroleptics (drugs which affect the brain and nervous system).
- antidepressants which belong to the group of medicines called monoamine oxidase inhibitors (MAOI). Treatment with MAOI should be stopped 14 days before the treatment with Tardiben starts.

Do not use Tardiben together with reserpine (medicine used to treat high blood pressure and psychotic symptoms).

Some medicines (e.g. fluoxetine, paroxetine, terbinafine, moclobemide and quinidine) may increase the level of tetrabenazine in the blood, and thus should only be combined with caution. A reduction of the tetrabenazine dose may be necessary.

Tardiben with food and alcohol

Drinking alcohol while you are taking Tardiben may cause you feel abnormally sleepy.

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking Tardiben. Your doctor will decide after taking all risks and benefits into account, if you may use Tardiben during pregnancy. Tardiben must not be taken by breast feeding mothers.

When animals were tested, a delay in female fertility was observed. The effect on fertility in humans has not been tested. If you are concerned, ask your doctor for advice.

Driving and using machines

Tardiben may cause somnolence and therefore may modify your performance at driving and using machines to a varying degree, depending on the dose and individual susceptibility.

Tardiben contains lactose

These tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Tardiben.

3. How to take Tardiben

Always take Tardiben exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Swallow the tablet(s) with water or another non-alcoholic drink.

Adults

Huntington's chorea

The recommended starting dose is half a tablet (12.5 mg) one to three times a day. This can be increased every three or four days by half a tablet until the optimal effect is observed or up to the occurrence of intolerance effects (sedation, Parkinsonism, depression).

The maximum daily dose is 8 tablets (200 mg) a day.

If you have taken the maximum dose for a period of seven days and your condition has not improved, it is unlikely that the medicinal product will be of benefit to you.

Tardive Dyskinesia

The recommended starting dose for patients with tardive dyskinesia is half a tablet (12.5 mg) a day, which can be increased as needed depending on your response to treatment. These tablets will be stopped if there is no clear benefit or if the side-effects become too much for you.

The elderly

The standard dosage has been administered to elderly patients without apparent side effects. However, Parkinson-like side effects are common.

Use in children

The treatment is not recommended in children.

Patients with hepatic disorder

Patients with mild to moderate hepatic disorders should start with half a tablet (12.5 mg) a day. For patients with severe hepatic disorders, additional caution is necessary.

Patient with renal disorder

Tardiben is not recommended for use in this patient group.

If you take more Tardiben than you should

If you take more Tardiben than you should or someone else accidentally takes your medicine, contact your doctor, pharmacist or nearest hospital straight away. You may develop somnolence, sweating, low blood pressure, and extremely low body temperature (hypothermia). Your doctor will treat the symptoms.

If you forget to take Tardiben

If you forget to take one dose, you should never make up for the missing dose by doubling it at the next time. Instead you should simply continue with the next dose when it is due.

If you stop taking Tardiben

Do not stop taking Tardiben unless your doctor tells you to. A neuroleptic malignant syndrome has been described after abrupt withdrawal of Tardiben.

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

4. Possible side effects

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

The following undesirable effects are ranked according to system organ class and to their frequency:

very common: affects more than 1 user in 10

common: affects 1 to 10 users in 100

uncommon: affects 1 to 10 users in 1,000

rare: affects 1 to 10 users in 10,000

very rare: affects less than 1 user in 10,000

not known: frequency cannot be estimated from the available data

Very common:

Somnolence (with higher dosages), depression, Parkinson-like syndrome (uncontrollable movements of the hands, arms, legs and head, with higher dosages)

Common:

Confusion, anxiety, sleeplessness, low blood pressure, dysphagia (difficulty in swallowing), nausea, vomiting, diarrhoea, constipation

Uncommon:

Mental changes such as confusion or hallucinations, muscular rigidity, hypothermia, autonomic dysfunction

Rare:

Neuroleptic Malignant Syndrome (NMS) (neurological disorder)

Very rare:

Skeletal muscle damage

For the following side-effects, it is not possible to estimate the incidence from available data:

disorientation, nervousness, ataxia and dystonia (loss of control of movements), akathisia (restlessness), dizziness, amnesia (memory loss), bradycardia (slow heart beat), epigastric pain (stomach pain), dry mouth, irregular menstrual cycle, feeling dizzy if you stand suddenly (especially when first getting out of bed or you have been sitting for a long time).

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). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tardiben

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

Do not use Tardiben after the expiry date which is stated on the bottle label and carton. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light.

Do not store above 25°C.

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 Tardiben contains

- The active substance is tetrabenazine.
- Each tablet contains 25 mg tetrabenazine.
- The other ingredients are: pre-gelatinised maize starch, lactose monohydrate, talc, ferric oxide yellow E172, magnesium stearate.

What Tardiben looks like and contents of the pack

Yellow, round, tablets with one-side break notch in white twist-off bottles available in two different pack-sizes:

One pack-size containing 42 tablets, the other pack-size containing 112 tablets.

Not all pack-sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

AOP Orphan Pharmaceuticals AG
Wilhelminenstrasse 91/II f
1160 Vienna
Austria

Manufacturer:

AOP Orphan Pharmaceuticals AG
Wilhelminenstrasse 91/II f
1160 Vienna
Austria

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria:	Dystardis 25 mg Tabletten
Bulgaria:	Dystardis 25 mg таблетки
Finland:	Dystardis 25 mg tabletit
Germany:	Dystardis 25 mg Tabletten
Norway:	Tardiben 25 mg tabletter
Poland:	Dystardis
Romania:	Artesyd 25 mg comprimate
Slovakia:	Dystardis 25 mg tablety
United Kingdom:	Tardiben 25 mg tablets

This leaflet was last revised in May 2018.