

Package leaflet: Information for the user
Tetrabenazine 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 effect not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Tetrabenazine is and what it is used for

Tetrabenazine is a medicine belonging to the group treating disorders of the nervous system. Tetrabenazine is used for the treatment of diseases causing jerky, irregular, uncontrollable movements (hyperkinetic motor disorders with Huntington's chorea).

2. What you need to know before you take Tetrabenazine

Do not take Tetrabenazine

- if you are allergic to tetrabenazine or any of the other ingredients of Tetrabenazine 25 mg tablets (listed in section 6).
- if you use reserpine (medicine to control high blood pressure and treat psychotic states).
- if you use a medicine which belongs to the group of drugs called monoamine oxidase (MAO) inhibitors (medicine to treat depression)
- if you have liver impairment
- if you suffer from Parkinson-like symptoms
- if you have a depression
- if you are having thoughts of harming or killing yourself
- if you are breast-feeding
- if you suffer from pheochromocytoma (tumour of the adrenal gland)
- if you suffer from pro-lactin-dependent tumours, e.g. pituitary or breast cancer

Warnings and precautions

Talk to your doctor or pharmacist before taking Tetrabenazine

- 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 fall 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 unpleasant sensations of inner restlessness, a compelling need to be in constant motion or disturbances in coordination of movements. Please consider that Tetrabenazine bind to melanin containing tissues which may affect your eyes.

Children

Tetrabenazine is not recommended in children

Other medicines and Tetrabenazine

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

Take special care if you use Tetrabenazine together with Levodopa (a medicine used to treat Parkinson's disease).

Do not use Tetrabenazine together with reserpine.

Treatment with MAO inhibitors should be stopped 14 days before the treatment with tetrabenazine starts. It is not recommended to use this medicine with certain types of antidepressants, alcohol, opioids, beta blockers, antihypertensive drugs (medicine to treat high blood pressure), hypnotics and neuroleptics (medicine to treat psychotic disorders).

Drugs which are inhibitors of CYP2D6 (e.g. fluoxetine, paroxetine, terbinafine, moclobemide and quinidine) may result in increased plasma concentrations of the active metabolite dihydrotetrabenazine. If you take such medicine, you may need a lower dose of Tetrabenazine.

Take special care if you use Tetrabenazine together with drugs known to prolong the QTc interval in the ECG, including some drug used to treat mental health conditions (neuroleptics), certain antibiotics (e.g. gatifloxacin, moxifloxacin) and some drugs used to treat problems with heart rhythm conditions (e.g. quinidine, procainamide, amiodarone, sotalol).

Pregnancy and breast-feeding

Tetrabenazine should not be taken during pregnancy, or when breast-feeding. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking Tetrabenazine.

Driving and using machines

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

Tetrabenazine 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 this medicinal product.

3. How to take Tetrabenazine

Always take Tetrabenazine exactly as your doctor has told you. 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.

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.

Patient with renal disorder

Tetrabenazine is not recommended for use in this patient group.

If you take more Tetrabenazine than you should

If you take more Tetrabenazine than you should, you may develop drowsiness, sweating, low blood pressure, and extremely low body temperature (hypothermia). Your doctor will treat the signs.

If you forget to take Tetrabenazine

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 Tetrabenazine

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

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

4. Possible side effects

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

The following undesirable effects are ranked according to frequency:

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

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

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

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

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

Mental changes such as confusion or hallucinations, stiffness in muscles, fever

Rare (may affect up to 1 in 1,000 people):

A condition called Neuroleptic Malignant Syndrome if you start to have mental changes such as confusion or hallucinations, or develop stiffness in your muscles and fever, you may be developing a condition called Neuroleptic Malignant Syndrome.

Very rare (may affect up to 1 in 10,000 people):

Muscle damage

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

disorientation, nervousness, problems with coordination of movements, feeling that you cannot sit or stand still (akathisia), uncontrollable muscle spasms (dystonia), dizziness, forgetfulness, slow heart rate,

dizziness when quickly standing up from a lying or sitting position, stomach pain, dry mouth, low body temperature.

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

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

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

5. How to store Tetrabenazine

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

Do not use Tetrabenazine after the expiry date which is stated on the bottle 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 to protect the environment.

6. Contents of the pack and other information

What Tetrabenazine contains

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

What Tetrabenazine looks like and contents of the pack

Yellow, round tablet, with a break line on one-side and `TE25` engraved on the reverse side.

Packed in white twist-off bottles with 112 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Walter Ritter GmbH + Co. KG

Spaldingstraße 110 B

20097 Hamburg, Germany

Manufacturer:

AOP Orphan Pharmaceuticals GmbH

Leopold-Ungar-Platz 2

1190 Vienna, Austria

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

Austria:	Tetmodis 25 mg Tabletten
Belgium:	Tetrabenazine AOP Orphan Pharmaceuticals 25 mg tabletten
Bulgaria:	ТЕТМОДИС 25 mg таблетки
Czech Republic:	Tetmodis
Denmark:	Tetmodis 25 mg tabletter
Estonia:	Tetmodis 25 mg tablett
Finland:	Tetmodis 25 mg tabletti
France:	Comprimés Tetmodis 25 mg
Germany:	Tetmodis 25 mg Tabletten
Greece:	Tetmodis 25 mg δισκία
Hungary:	Motetis 25 mg tableta
Ireland:	Tetrabenazine 25 mg tablets
Latvia:	Tetmodis 25 mg tabletes
Lithuania:	Tetmodis 25 mg tabletes
Netherlands:	Tetmodis 25 mg tabletten
Poland:	Tetmodis 25 mg tabletki
Portugal:	Comprimidos de Tetmodis 25 mg
Romania:	Tetmodis, tablete, 25 mg
Slovakia:	Tetmodis 25 mg tableta
Slovenia:	Tetmodis 25 mg tablete
Spain:	Tetmodis 25 mg comprimidos
Sweden:	Tetmodis 25 mg tablett
United Kingdom:	Tetrabenazine 25 mg tablets

This leaflet was last revised in