

PACKAGE LEAFLET

Package leaflet: Information for the patient

Tetrabenazine 25 mg Tablets

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 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 affects some of the chemicals that are released by the nerves in the brain which helps to control jerky and irregular movements of the body (called chorea).

Tetrabenazine is used for the treatment of jerky, irregular uncontrollable movements that can be caused by conditions such as Huntington's chorea, senile chorea and hemiballismus.

Tetrabenazine is also used for treatment of 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.
- Tetrabenazine should only be given to you for treatment of tardive dyskinesia when symptoms are moderate to severe, disabling, and/or embarrassing in social situations.
- Tetrabenazine 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 Tetrabenazine

Do not take Tetrabenazine

- If you are allergic to tetrabenazine or any of the other ingredients of the medicine (listed in section 6).
- If you are actively suicidal (feel like killing yourself).
- If you are breast-feeding.
- If you have been diagnosed as having depression that has been untreated or difficult to treat.
- If you are taking antidepressants which belong to the group of medicines called monoamine oxidase inhibitors or MAOIs or have taken them at any time in the last two weeks.
- If you have liver trouble.
- If you have been diagnosed as having parkinsonism and hypokinetic-rigid syndrome. The signs of parkinsonism are trembling in the hands or jerky movements in the arms and legs.

Warnings and precautions

Talk to your doctor before taking Tetrabenazine:

- If you have been diagnosed with depression or have thought about or tried to commit suicide.
- If you have ever had depression.
- If you start to experience angry or aggressive behaviour.

- If you have a heart condition known as long QT syndrome. Tetrabenazine should be used with caution with other medicines known to prolong QT syndrome (see “Other medicines and Tetrabenazine” section) and in patients with congenital QT syndromes and a history of cardiac arrhythmias.
- If you have a recent history of chest pain or heart disease.
- If you have ever had trembling in the hands and jerky movements in the arms and legs, known as parkinsonism.
- 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 difficulty in swallowing.
- If you have a reaction with worm-like movements of the tongue or other uncontrolled movements of the mouth, tongue, cheeks, or jaws, which may progress to the arms and legs (tardive dyskinesia).
- If you feel restless, agitated, or have difficulty sitting still.
- If you experience dizziness or light-headedness when standing.
- If you have hyperprolactinemia (higher-than-normal blood levels of the hormone prolactin – the hormone responsible for lactation).
- If you have problems digesting certain sugars, such as galactose.
- 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.

Children

Tetrabenazine should not be used in children.

Other medicines and Tetrabenazine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription. This includes herbal medicines.

Medicines which **may interact** with or be affected by Tetrabenazine:

- Levodopa used to treat Parkinson’s disease.
- Antidepressants which belong to the group of medicines called monoamine oxidase inhibitors (or MAOIs). At least 14 days should lapse between the discontinuation of MAOIs and initiation of treatment with Tetrabenazine.
- Medicines which affect the brain and nervous system such as haloperidol, chlorpromazine, and thioridazine (called neuroleptic medicines).
- Metoclopramide used to treat nausea and vomiting.
- Strong painkillers such as morphine and codeine (opioids).
- Medicines to help sleep (hypnotics).
- Medicines used to treat high blood pressure (anti-hypertensives and beta blockers).
- Anti-depressant medicines such as fluoxetine, paroxetine.
- Certain antibiotics e.g. gatifloxacin, moxifloxacin.
- Some medicines used to treat problems with heart rhythm conditions e.g. quinidine, procainamide, amiodarone, sotalol.

Taking Tetrabenazine with food and drink

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

Pregnancy, breast-feeding and fertility

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

Pregnancy

Tetrabenazine should not be taken during pregnancy.

Breast-feeding

Tetrabenazine should not be taken when breast-feeding.

Fertility

When animals were tested, a delay in fertility was seen. The effect on fertility in humans has not been tested.

Driving and using machines

Tetrabenazine may cause drowsiness. If affected, do not drive or operate machinery.

Tetrabenazine contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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.

- The tablet can be divided into equal doses. Swallow with water or another non-alcoholic drink.
- For patients with uncontrollable movements caused by conditions such as Huntington's chorea, if there is no improvement at the maximum dose in 7 days, it is unlikely that the medicine will be of benefit to you. If you have any concerns, please talk to your doctor.
- If you get certain side effects, your dosage will be reduced.
- Do not change the prescribed dose yourself. If you think the effect of your medicine is too weak or too strong, talk to your doctor. Always tell your doctor if you want to stop taking your medicine.

Adults

Uncontrollable movements caused by conditions such as Huntington's chorea:

- The recommended starting dose is half a tablet (12.5 mg) to one tablet (25 mg) every day.
- The dose is usually increased gradually by your doctor to a maximum of eight tablets a day (a total of 200 mg), depending on any side effects you may experience.
- Tablets should then be taken two or three times daily, as instructed by your doctor.

Tardive Dyskinesia:

- The recommended starting dose is half a tablet (12.5 mg) a day, which may be increased by your doctor as needed depending on your response to treatment.

Elderly patients

Your doctor will decide the best dose for you if you are elderly.

Use in children

Tetrabenazine should normally not be used in children. If your doctor decides your child should take this medicine, they will tell you how much to take.

If you take more Tetrabenazine than you should

If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you.

Symptoms of overdose include: Uncontrollable muscle spasms affecting the eyes, head, neck and body, uncontrolled rolling of the eyes, excessive eye blinking, nausea, vomiting, diarrhoea, sweating, dizziness, feeling cold, confusion, hallucinations and drowsiness, redness/inflammation, and tremor.

If you forget to take Tetrabenazine

Take it as soon as you remember, unless it is nearly time for your next dose. If you miss a dose, do **not** take a double dose to make up for a forgotten dose.

If you stop taking Tetrabenazine

It is important that you keep taking Tetrabenazine for as long as your doctor has told you to. Your doctor will decide when your treatment can be stopped. They may decide to gradually reduce the dose, although it may not be necessary.

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

4. Possible side effects

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

Seek medical advice immediately if you experience the following side effects:

- Allergic reaction: swelling of the face, throat or tongue, difficulty breathing or dizziness (anaphylaxis).
- Tetrabenazine can cause depression, which can lead to thoughts of committing suicide. If you feel down or very sad you may be starting to become depressed and you should tell your doctor about this change.
- If you feel restless and feel that you can't sit still, you may have a condition called akathisia.
- If you develop trembling or uncontrollable movements in your hands, arms, legs and head, drooling, problems swallowing, or problems with your balance you may have a condition called parkinsonism.
- If you have tried to commit suicide.
- 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 intentionally hurt yourself or if you have started to think about intentionally hurting yourself.
- If you have a severe increase in blood pressure (hypertensive crisis).

Other side effects:**Very common** (may affect more than 1 in 10 people)

- Anxiety, restlessness.
- Confusion.
- Movement disorders.
- Sleepiness, problems with sleeping (insomnia), tiredness.
- Involuntary blinking or eye spasms.
- Cough, sore throat, runny nose, nasal congestion, headache, low grade fever, facial pressure and sneezing (upper respiratory tract infection).
- Feeling sick.
- Falls.

Common (may affect up to 1 in 10 people)

- Decreased appetite.
- Feeling agitated or irritable.
- Anxiety characterised by intrusive thoughts that produce uneasiness, apprehension, fear or worry and by repetitive behaviours (Obsessive Compulsive Disorder).
- Difficulty balancing.
- Slowness in moving.
- Uncontrollable muscle spasms affecting the eyes, head, neck, and body.
- Lack of energy.
- Dizziness.
- Difficulty in speaking.
- Headache.

- Fever, chills, shortness of breath, cough, chest pain and dizziness, phlegm and occasionally blood (pneumonia).
- Shortness of breath.
- A cough that often brings up mucus, as well as shortness of breath, wheezing, and chest tightness (bronchitis).
- Diarrhoea.
- Vomiting.
- Constipation.
- Pain when passing urine.
- Bruising, cuts.
- Self-inflicted injuries.

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

- Difficulty in swallowing.

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

- Frequent infections such as fever, severe chills, sore throat, or mouth ulcers.
- Feeling aggressive or angry.
- Nervousness.
- Sleep disorder.
- Clumsiness and lack of co-ordination, affecting balance and manner of walking, limb or eye movements and/or speech.
- Tremor.
- Fast or irregular heartbeat (palpitations).
- Uncontrolled rolling of the eyes.
- Sensitivity to sunlight.
- Blurred vision (due to hypertension).
- Dehydration.
- Excess salivation.
- Cough.
- Pneumonia with choking (pneumonia aspiration).
- Dry mouth.
- Excessive sweating.
- Rash, itching, hives.
- Urge to urinate with a possible burning sensation (urinary tract infection).
- Problems with or having no menstrual periods.
- Generally feeling unwell.
- Fever, high temperature or feeling hot.
- Weight loss.
- Taking more medicine than prescribed by your doctor (see “If you take more Tetrabenazine than you should” section).

Not known (frequency cannot be estimated from the available data)

- Memory loss.
- Feeling dizzy when standing up after sitting or lying down.
- Abnormal liver test results, which may indicate liver damage.
- Weakness.
- Dizziness and postural hypotension (sudden dizziness and fainting when standing up).
- Increased appetite, increased body weight.

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 at:

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 Tetrabenazine

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/label after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in the original package in order to protect from light.

Medicines should not be disposed of 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 Tablets contains:

Each tablet contains 25 mg of tetrabenazine.

The other ingredients are: lactose monohydrate, maize starch, cellulose microcrystalline, talc, magnesium stearate, iron oxide yellow (E172).

What Tetrabenazine looks like and contents of the pack:

Tetrabenazine are pale yellow, circular, flat-faced, bevel-edged, uncoated tablets with a deep break-line score-line on one side and the other side is plain.

The tablet has a diameter of 7 mm and a thickness of 2.3 mm to 2.9 mm.

Tetrabenazine is available in a bottle containing 112 tablets.

Marketing Authorisation Holder

Tillomed Laboratories Limited
220 Butterfield
Great Marlings
Luton
LU2 8DL
United Kingdom

Manufacturer

Tillomed Laboratories Limited
220 Butterfield
Great Marlings
Luton
LU2 8DL
United Kingdom

Tillomed Malta Limited
Malta Life Sciences Park
LS2.01.06 Industrial Estate
San Gwann
SGN 3000
Malta

This leaflet was last revised in March 2026

Till-Manx V.1.2