

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

This medicine is dispensed by doctor's prescription only

Xenazine[®] 25 mg, Tablets

Active ingredient: each tablet contains: Tetrabenazine 25 mg

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 with your doctor or pharmacist. This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar.

Xenazine 25 mg affects several chemical substances that are released in the brain and help to control abnormal and involuntary movements of the body.

1. What is this medicine intended for?

Xenazine 25 mg is prescribed to treat diseases that cause sudden uncontrollable abnormal movements, such as Huntington's chorea, senile chorea, tardive dyskinesia and hemiballismus.

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 tetrabenazine or to any of the other ingredients of the medicine (see section 6).
- You are actively suicidal (you feel like you want to commit suicide).
- You are breastfeeding.
- You have been diagnosed with depression that is untreated or not responding to treatment.
- You are taking antidepressants belonging to the group of medicines called monoamine oxidase inhibitors (MAOIs) or have taken such medicines at any time during the last two weeks.
- You have liver problems.
- You have been diagnosed with parkinsonism and/or hypokinetic-rigid syndrome. The symptoms of parkinsonism are hand tremors or abnormal arm and leg movements.

Special warnings about using this medicine

Before using Xenazine 25 mg, tell your doctor if:

- You have been diagnosed with depression or have suicidal thoughts or have attempted to commit suicide.
- You have had depression at any time.
- You start showing angry or aggressive behavior.
- You have a heart problem known as Long QT syndrome. Caution should be exercised when using tetrabenazine concomitantly with other medicines known to prolong QT syndrome (listed under 'Drug interactions') and by patients with congenital QT syndromes and a history of cardiac arrhythmias.
- You have a recent history of chest pain or heart disease.
- You have ever had hand tremors and jerky movements in your arms and legs at any time, which is known as Parkinson's disease).
- You start experiencing mental changes, such as confusion or hallucinations, or developing stiffness in your muscles and a fever. You may be developing a condition called neuroleptic malignant syndrome. If you have these symptoms, **go to your doctor immediately.**
- You start having difficulty swallowing.
- You have a reaction of worm-like tongue movements or other uncontrollable movements of your mouth, tongue, cheeks or jaws, which may progress to your arms and legs (tardive dyskinesia).
- You feel restless, agitated or have difficulty sitting still.
- You experience dizziness or lightheadedness when standing up.
- You have hyperprolactinemia (elevated level of the hormone prolactin – the hormone responsible for lactation).
- You have problems digesting particular sugars, such as galactose.

- You know that your body metabolizes an enzyme called CYP2D6 slowly or moderately, because, in such instance, a different dosage may be suitable for you.

Children

The medicine is not intended for children since its safety and efficacy for this population have not been examined.

Adults

Parkinson-like side effects are quite common among this population, and dosage adjustment may be needed.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medications and dietary supplements, inform your doctor or pharmacist, especially if you are taking:

- Levodopa, which is used to treat Parkinson's disease.
- Antidepressants belonging to the group of medicines called monoamine oxidase inhibitors (MAOIs). At least 14 days should elapse between the discontinuation of MAOIs and starting treatment with Xenazine 25 mg.
- Medicines that affect the brain and nervous system, such as haloperidol, chlorpromazine and thioridazine (called neuroleptic medicines).
- Metoclopramide, which is used to treat nausea and vomiting.
- Strong painkillers, such as morphine and codeine (opioids).
- Medicines to help you sleep (sleeping pills).
- Medicines used to treat high blood pressure (antihypertensives and beta-blockers).
- Antidepressant medicines, such as fluoxetine, paroxetine.
- Particular antibiotics, such as gatifloxacin, moxifloxacin.
- Particular medicines used to treat heart rhythm problems, such as quinidine, procainamide, amiodarone, sotalol.

Taking Xenazine and food

Xenazine 25 mg can be taken with or without food.

Using this medicine and alcohol consumption

Drinking alcohol while taking Xenazine 25 mg may cause you to feel very drowsy.

Pregnancy, breastfeeding and fertility

If you are pregnant, think you might be pregnant or are planning to become pregnant, you should consult with your doctor, who will explain the possible effect of Xenazine 25 mg on your unborn child.

Xenazine 25 mg should not be taken during pregnancy or when breastfeeding.

Delayed fertility has been found during tests on animals. The effect on human fertility has not been examined. If you are concerned, consult with your doctor.

Driving and using machines

Xenazine 25 mg may cause drowsiness and other side effects.

Depending upon your response to this medicine, you may find that your ability to drive a car or operate machinery is affected.

Important information about some of this medicine's ingredients

Xenazine contains lactose (64 mg per tablet). If you have been told by your doctor that you have an intolerance to particular sugars, consult with your doctor before taking this medicine.

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 the dosage or about how to take this medicine. Only your doctor will determine your dosage and how you should take this medicine. The recommended dosage is usually:

- The starting dosage is usually 25 mg three times per day. The doctor will usually increase the dosage gradually by one tablet per day, every three or four days. The maximum dosage is 200 mg per day (eight tablets per day).
- The starting dosage recommended for people with tardive dyskinesia is half a tablet (12.5 mg) per day. Your doctor may increase the dosage depending upon your response to the treatment.
- Your doctor will discontinue the treatment if your condition does not improve or if the side effects

become intolerable for you.

- Do not change the dosage on your own. Consult with your doctor if it seems to you that the effect of the medicine is too strong or too weak.
- Your doctor will decide the suitable dosage for children and adults.

Do not exceed the recommended dose.

- Swallow the medicine with water or any nonalcoholic beverage.
- Do not chew the tablet. The tablet can be split into equal halves.

If you have accidentally taken a higher dose or if a child has accidentally swallowed some of the medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. Symptoms of overdose: nausea, vomiting, diarrhea, sweating, dizziness, chills, confusion, hallucinations, drowsiness, low blood pressure, high body temperature.

If you forget to take the medicine at the scheduled time, take it as soon as you remember. Do not take a double dose to compensate for the dose you forgot to take. If you forget to take more than one tablet, consult with your doctor.

If you stop taking this medicine

Even if your health improves, do not stop taking this medicine without consulting with 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 with your doctor or pharmacist.

4. Side effects

Like with all medicine, Xenazine 25 mg may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Go immediately to your doctor or to an emergency room if you experience any of the following side effects:

Very common side effects (affecting more than 1 in 10 users):

- Xenazine 25 mg can cause depression, which may lead to suicidal ideation. If you feel despondent or very sad, you may be starting to develop depression and you should tell your doctor about this change.
- If you feel restless and cannot sit still, you may have a symptom called akathisia. If you feel like this, go to your doctor.

Common side effects (affecting 1-10 in 100 users):

- If you develop tremors or uncontrollable movements in your hands, arms, legs and head, drooling, problems swallowing or problems with your balance, you may have something called parkinsonism. If you have any of these problems, go to your doctor.

Very rare side effects (affecting less than 1 in 10,000 users):

- If you attempted suicide.
- If you start experiencing mental changes, such as confusion or hallucinations, or developing stiffness in your muscles and a fever, you may be developing a condition called neuroleptic malignant syndrome. If you discern these symptoms, go to your doctor immediately.
- If you have intentionally hurt yourself or have started thinking about intentionally hurting yourself.

Side effects of unknown frequency:

- If you have a sharp rise in blood pressure (hypertensive crisis).

Consult with a doctor as soon as possible if you experience any of the following side effects:

Very common side effects (affecting more than 1 in 10 users):

- Anxiety, confusion or restlessness.
- Impaired mobility.
- Drowsiness.
- Problems sleeping (insomnia).
- Involuntary blinking or eye spasms.

- Specific symptoms/signs of upper respiratory tract infection: cough, sore throat, runny nose, nasal congestion, headache, low-grade fever, facial pressure and sneezing.
- Nausea.
- Tiredness.
- Falls.

Common side effects (affecting 1-10 in 100 users):

- Decreased appetite.
- Agitation or irritability.
- Anxiety characterized by troubling thoughts causing uneasiness, apprehension, fear or worry and by repetitive behaviors in attempts to alleviate the associated anxiety (obsessive-compulsive disorder).
- Loss of balance.
- Slowed movement.
- Uncontrollable muscle spasms affecting the eyes, head, neck and body.
- Lack of energy.
- Dizziness.
- Difficulty speaking.
- Headache.
- Specific symptoms/signs of pneumonia: fever, shivers, shortness of breath, cough, chest pain and dizziness, phlegm and occasionally bloody sputum.
- Shortness of breath.
- Specific symptoms/signs of bronchitis: cough that often brings up mucus, as well as shortness of breath, wheezing and chest tightness.
- Diarrhea.
- Vomiting.
- Constipation.
- Pain when urinating.
- Bruises, cuts.
- Self-inflicted injuries.

Rare side effects (affecting 1-10 in 10,000 users):

- Difficulty swallowing.

Very rare side effects (affecting less than 1 in 10,000 users):

- Frequent infections, such as fever, severe shivering, sore throat or mouth ulcers.
- Feelings of aggression or anger.
- Agitation.
- Insomnia.
- Clumsiness and lack of coordination affecting: balance and walking, limb or eye movements and/or speech disorders.
- Tremors.
- Fast or irregular heartbeat (palpitations).
- Uncontrollable rolling of the eyes, sensitivity to sunlight, blurred vision (due to hypertension), allergic reaction, interactions with other medicines, abnormal sensitivity or allergy to the medicine.
- Dehydration.
- Excessive salivation.
- Cough.
- Pneumonia with choking (pneumonia aspiration – pneumonia resulting from the aspiration of food into the airways).
- Dry mouth.
- Excessive sweating.
- Rash, itching, urticaria.
- Urinary urgency, possibly accompanied by a burning sensation (urinary tract infection).
- Irregular menstruation or absent menstruation.
- General feeling of being unwell.
- Fever, high temperature or feeling hot.
- Weight loss.
- Taking a larger quantity of medicine than prescribed by your doctor (if you took too much Xenazine 25 mg).

Side effects of unknown frequency:

- Memory loss.
- Feeling dizzy when rising from a sitting or lying position.
- 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.

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 with your doctor.

Reporting of 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's 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/>.

In addition, you can report by sending an e-mail to the registration-holder's Patient Safety Unit: drugsafety@neopharmgroup.com

5. How to store the medicine?

- Avoid 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 outer package. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Use within 3 months after first opening.

6. Additional information

In addition to the active ingredient (tetrabenazine), this medicine also contains: maize starch, lactose, talc, magnesium stearate, iron oxide-yellow E172.

What does the medicine look like, and the contents of the pack:

Xenazine 25 mg – yellowish-buff, circular, bevel-edged tablets with 'CL 25' printed on one face and a single score line on the other.

The tablets are packed in a white plastic bottle with a childproof safety cap. Each bottle contains 112 tablets.

Registration-holder's name and address: Neopharm Ltd., 6 Hashiloach St., POB 7063, Petach Tikva 4917001, Israel.

Manufacturer's name and address: Recipharm Fontaine, Fontaine-les-Dijon, France, for Valeant Pharmaceuticals, Dublin, Ireland.

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Registration number of the medicine in the Ministry of Health's National Drug Registry:

Xenazine 25 mg - 132-07-31010-01.