

**Package leaflet: Information for the patient**  
**<Product name> 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 <Product name> is and what it is used for
2. What you need to know before you take <Product name>
3. How to take <Product name>
4. Possible side effects
5. How to store <Product name>
6. Contents of the pack and other information

**1. What <Product name> is and what it is used for**

<Product name> contains a substance called tetrabenazine. This 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. <Product name> is used in adults for the treatment of Huntington's chorea, which cause jerky, irregular uncontrollable movements.

**2. What you need to know before you take <Product name>**

**Do not take <Product name>**

- if you are allergic to tetrabenazine or any of the other ingredients of this medicine (listed in section 6)
- if you are breast-feeding
- if you have liver impairment (Child-Pugh class A, B and C, score  $\geq 5$ )
- if you have been diagnosed as having depression and this has been difficult to treat
- if you have used during last 14 days antidepressants or other medicines which belong to the group of drugs called monoamine oxidase inhibitors (MAOI)
- if you have thought about or tried to commit suicide
- if you have used during last 20 days reserpine, a medicine used sometimes to control Huntington's disease
- if you have certain type of parkinsonism with stiff (rigid) muscles and movement difficulties.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking <Product name>

- if you have a heart condition known as long QT syndrome or you are taking medicines which may cause it, for instance certain antipsychotic medications (e.g. chlorpromazine, thioridazine), antibiotics (e.g. gatifloxacin, moxifloxacin) and class IA and III antiarrhythmic medications (e.g. quinidine, procainamide, amiodarone, sotalol)
- if you have unstable angina or have had recently heart attack
- if you have mild to moderate renal impairment.

- if you have low mood (feeling down, sad, or depressive)
- if you have any thoughts or feelings about hurting yourself. Suicidal thoughts and behaviours have been reported during tetrabenazine treatment
- if you feel anger and have thoughts to harm things around you or other people

Talk to your doctor or pharmacist immediately

- if you have developed during the treatment restlessness (akathisia, agitation)
- jerky involuntary movements in the arms and legs (tardive dyskinesia)
- a decrease in vision
- if you suffer from muscle stiffness or inflexibility with high fever, sweating, altered mental status, or very rapid or irregular heart beat (Neuroleptic Malignant Syndrome)
- if you feel excessive sleepiness (somnolence)

### **Other medicines and <Product name>**

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

Some medicines can cause problems if you take them with tetrabenazine. These are:

- antidepressants and other medicines from the group of drugs called monoamine oxidase inhibitors (MAOIs), see Do not take <Product name> above
- reserpine should not be used within 20 days before <Product name>
- levodopa used to treat Parkinson's disease
- antipsychotics (e.g. haloperidol, chlorpromazine, thioridazine), metoclopramide, strong painkillers and medication to help sleep
- antidepressants fluoxetine, paroxetine, fluvoxamine and bupropion
- antifungals such as ketoconazole
- HIV-protease inhibitors, such as ritonavir
- drugs used to treat high blood pressure or arrhythmias (e.g. beta-blockers)
- certain antibiotics (e.g. ciprofloxacin, gatifloxacin, moxifloxacin)
- some drugs used to treat problems with heart rhythm disorders e.g. quinidine, procainamide, amiodarone, sotalol).

### **<Product name> with food, drink and alcohol**

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

<Product name> can be taken without regard to meals.

### **Pregnancy, breast feeding and fertility**

#### Pregnancy

<Product name> is not recommended during pregnancy and in women of childbearing potential not using contraception. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

#### Breast-feeding

You should not breast-feed while you are taking <Product name> (see section 2, Do not take <Product name>).

### **Driving and using machines**

<Product name> has moderate to major influence on the ability to drive and use machines, as it very commonly causes somnolence, akathisia and parkinsonism.

You alone are responsible to decide if you are in a fit condition to drive a motor vehicle or perform other tasks that demand increased concentration. One of the factors that can reduce your ability to do these things safely is your use of medicines that can cause these effects or undesirable effects.

Descriptions of these effects can be found in other sections. Read all the information in this leaflet for guidance. Discuss with your doctor, nurse or pharmacist if you are unsure about anything.

**<Product name> contains 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 <Product name>**

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

The recommended dose is:

- the usual starting dose for adults is a half of the tablet (12,5 mg) once a day for the first week
- this is usually increased by a half of the tablet (12,5 mg) twice a day for the second week
- when needed, dose can be further increased to a half of the tablet (12,5 mg) three times a day for the third week
- subsequent dose increments can be made with weekly intervals by a half of tablet (12,5 mg) each time
- individual optimal doses range usually between 25-100mg/day divided into two or three doses
- maximum single dose 37,5 mg should not be exceeded
- maximum daily dose 100 mg should not be exceeded.

Contact your doctor immediately if you get any adverse reaction, it may be necessary to reduce your dose or increasing of dosage was too fast. Some patients may respond to reduced doses and slower up-titration.

If there is no improvement at the maximum dose in seven days, it is unlikely that further increasing the dose or extending the duration of treatment will provide any further benefit.

#### **Use in children and adolescents**

There is no relevant use of Xenazine in children or adolescents. This product may not to be used in children or adolescents.

#### **Elderly patients**

Elderly patients may be more sensitive to side effects and may need lower dosage and prolonged up-titration.

#### **If you take more <Product name> than you should**

If you have taken more <Product name> than you should, or if children have been taking medicine by accident, please contact your doctor or the hospital to get an opinion of the risk and advice on action to be taken. Take package with you.

#### **If you forget to take <Product name>**

Do not take a double dose to make up for the forgotten dose. Continue with the next dose when it is due.

#### **If you stop taking <Product name>**

Do not stop taking <Product name> without consulting with your doctor before.

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.

**Inform your doctor immediately if any of the following develops during treatment with <Product name>**

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

- depression (feeling down or sad)
- akathisia (restlessness, feeling that you can't sit or stand still)
- parkinsonism (such as muscle stiffness, trembling and problems with your gait and balance).

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

- agitation
- anxiety (uneasiness)
- confusion.

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

- thoughts of committing suicide
- feeling anger or having behaved aggressively
- high fever, sweating, muscle stiffness, fast or irregular pulse or abnormal heart rhythm (neuroleptic malignant syndrome, NMS)
- pneumonia (patients with difficulties with swallowing may have increased risk)
- sustained upward deviation of the eyeballs (oculogyric crisis).

Side effects **with not known frequency** (*frequency cannot be estimated from the available data*)

- dizziness and postural hypotension (sudden dizziness when standing up)
- bradycardia (slowing of the heart rate)

**Below are listed other known side effects**

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

- somnolence (sleepiness)
- tremor
- excess salivation drooling.

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

- insomnia (difficulties in sleeping).

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

- reduction in ability to fight infections because of a lower level of white blood cells (leukopenia)
- decreased appetite, dehydration (lack of water inside the body), decreased body weight
- sensitivity to sunlight (photophobia)
- rash, pruritus or urticaria
- falls.

Side effects **with not known frequency** (*frequency cannot be estimated from the available data*)

- disorientation, nervousness, restlessness, sleep disorders
- ataxia, dystonia
- memory loss
- hypertensive crisis
- problems with swallowing, nausea, vomiting, epigastric pain, diarrhoea, constipation, dry mouth
- sweating (hyperhidrosis)

- irregular or missing menstrual cycle in females
- fatigue, weakness, hypothermia (low body temperature)
- abnormal laboratory tests (elevated ALT, elevated AST)
- hyperprolactinemia (may cause disturbances such as secretion from the breasts, growth of breasts (in males) or sexual problems, such as impotence).

### **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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store <Product name>**

This medicinal product does not require any special temperature storage conditions.

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

After opening the bottle use this medicine within 3 months.

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 <Product name> contains**

The active substance is tetrabenazine 25mg of tetrabenazine in each tablet.

The other ingredients are lactose monohydrate, maize starch, talc, magnesium stearate and the colorant iron oxide yellow (E172).

### **What <Product name> looks like and contents of the pack**

The tablets are yellowish, cylindrical, bevel-edged of 7 mm in diameter with 'CL25' on one side and score-line on the other.

Pack: HDPE bottles with 112 tablets.

### **Marketing Authorisation Holder**

PharmaSwiss Česká republika s.r.o.

Jankovcova 1569/2c

170 00 Prague

Czech Republic

### **Manufacturers**

Recipharm Fontaine S.A.S., Rue des Près Potets, 21121, Fontaine-Lès-Dijon, France

ICN Polfa Rzeszów S.A., 2, Przemysłowa, 35-959 Rzeszów, Poland

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

Finland, Czech Republic, Estonia, Greece, Hungary, Lithuania, Latvia, Poland, Romania, Slovakia, Slovenia: XENAZINE 25 mg

### **This leaflet was last revised in:**

**dd.mm.yyyy**