

**PACKAGE LEAFLET**

## Package leaflet: Information for the user

### Tetrabenazine 12.5 mg tablets 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 effects not listed in this leaflet. See section 4.

#### **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 belongs to a group of medicines used to treat 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 (hypersensitive) to tetrabenazine or any of the other ingredients of this medicine (listed in section 6)
- if you use reserpine (medicine to control high blood pressure and treat psychotic states)
- if you use MAO inhibitors (medicine to treat depression)
- if you suffer from Parkinson-like symptoms
- if you have been diagnosed as having depression and this has not been treated or has been difficult to treat
- if you are actively suicidal (feel like 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 know you are a slow or intermediate metaboliser of an enzyme called CYP2D6, because a different dose may be applicable to you
- if you are suffering from mild to severe liver problems
- 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 have been diagnosed with depression or have thought about or tried to commit suicide
- if you have ever had depression
- if you feel restless, agitated, -or have difficulty sitting still
- if you experience dizziness or lightheadedness when standing
- if you have hyperprolactinemia (higher-than-normal blood levels of the hormone prolactin – the hormone responsible for lactation)
- 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.

### **Other medicines and Tetrabenazine**

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

### **Taking other medicines**

Do not use Tetrabenazine together with reserpine.

Treatment with MAO inhibitors should be stopped 14 days before the treatment with Tetrabenazine starts, and MAO inhibitors should not be used until at least 14 days have elapsed after the treatment with Tetrabenazine has ended.

Talk to your doctor or pharmacist before you use Tetrabenazine together with

- levodopa (a medicine used to treat Parkinson's disease)
- certain types of antidepressants, opioids, beta-blockers, antihypertensive drugs (medicine to treat high blood pressure), hypnotics and neuroleptics (medicine to treat psychotic disorders)
- inhibitors of CYP2D6 (e.g. fluoxetine, paroxetine, terbinafine, moclobemide and quinidine). Use of these together with tetrabenazine may result in increased plasma concentrations of the active metabolite dihydrotetrabenazine; that is why they should only be combined with caution. A reduction of the tetrabenazine dose may be necessary.
- 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).

### **Tetrabenazine with alcohol**

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

### **Pregnancy and breast-feeding**

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will decide after taking all risks and benefits into account, if you may use Tetrabenazine during pregnancy.

Tetrabenazine must not be taken by breast feeding mothers. If treatment with tetrabenazine is necessary, breast-feeding must be stopped.

### **Driving and using machines**

Tetrabenazine may cause drowsiness and depending on how you respond to this medicine you may find that your ability to drive or operate machinery is affected.

### **Tetrabenazine contains lactose**

This medicine 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.

### **Tetrabenazine contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

### **3. How to take Tetrabenazine**

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

#### **Adults**

The recommended starting dose is 12.5 mg one to three times a day. This can be increased by 12.5 mg every three or four days as needed depending on your response to treatment.

The maximum daily dose is eight 25 mg tablets or sixteen 12.5 mg tablets (a total of 200 mg).

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

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

#### **Use in elderly patients**

The standard dosage has been administered to elderly patients without apparent ill effect. Parkinson-like adverse reactions are quite common in these patients.

#### **Use in children**

The treatment is not recommended in children.

#### **Patients with liver disorders**

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

#### **Patients with kidney disorders**

Tetrabenazine is not recommended for use in this patient group.

#### **If you take more Tetrabenazine than you should**

If you take too many tablets or someone else accidentally takes your medicine, contact your doctor, pharmacist, or nearest hospital straight away. 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, drowsiness, redness/inflammation, and tremor.

#### **If you forget to take Tetrabenazine**

Do not take a double dose to make up for a forgotten dose. 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 (NMS) has been described after abrupt withdrawal of tetrabenazine (see section 4, Rare side effects).

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.

#### **Most serious side effects**

Please seek advice immediately or go to your emergency department if you experience the following side effects:

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

- Tetrabenazine SUN can cause depression, which can, in some people, 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.

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

- if you have tried to commit suicide
- if you have intentionally hurt yourself or if you have started to think about intentionally hurting yourself
- if you have feelings of anger or aggression.

**Other side-effects**

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

- drowsiness (with higher dosages)
- 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
- constipation
- autonomic dysfunction (sweating and fluctuations in blood pressure).

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

- mental changes such as confusion or hallucinations
- stiffness in your muscles
- fever.

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

- a condition called Neuroleptic Malignant Syndrome (NMS).  
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 (NMS). NMS has been described after abrupt withdrawal of tetrabenazine.

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

- muscle damage.

**Frequency unknown (not possible to estimate the incidence from available data)**

- disorientation
- nervousness
- coordination problems
- uncontrollable and sometimes painful muscle spasms (dystonia)
- feeling that you cannot sit or stand still (akathisia)
- dizziness
- forgetfulness
- slowing of the heart rate
- stomach pain

- dry mouth
- increased appetite
- weight increase.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. 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](http://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 label after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Tetrabenazine contains**

#### *12.5 mg tablets*

- The active substance is tetrabenazine. Each tablet contains 12.5 mg of tetrabenazine.
- The other ingredients are lactose anhydrous, maize starch, sodium starch glycolate, talc, silica, colloidal anhydrous, and magnesium stearate.

#### *25 mg tablets*

- The active substance is tetrabenazine. Each tablet contains 25 mg of tetrabenazine.
- The other ingredients are lactose anhydrous, maize starch, sodium starch glycolate, iron oxide yellow (E172), talc, silica, colloidal anhydrous, and magnesium stearate.

### **What Tetrabenazine looks like and contents of the pack**

**Tetrabenazine 12.5 mg tablets:** This medicine is presented as a white to off-white, circular, flat faced bevelled edge uncoated tablet debossed with “1” on one side and plain on the other side.

**Tetrabenazine 25 mg tablets:** This medicine is presented as a yellow, circular, flat faced bevelled edge uncoated tablet debossed with “179” on one side and scored on the other side. The tablet can be divided into equal halves.

Tetrabenazine is supplied in plastic tablet containers each containing 112 tablets.

### **Marketing Authorisation Holder and Manufacturer**

Sun Pharmaceutical Industries Europe B.V.  
Polarisavenue 87  
2132 JH Hoofddorp  
The Netherlands

**This medicine is authorised in the Member states of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:**

Germany:	Tetrabenazin-neuraxpharm 12,5 mg/ 25 mg Tabletten
Italy:	Tetrabenazina SUN 12,5 mg/ 25 mg compresse
Netherlands:	Tetrabenazine SUN 12,5 mg/ 25 mg tabletten
Spain:	Tetrabenazina SUN 25 mg comprimidos EFG
United Kingdom (Northern Ireland):	Tetrabenazine 12.5 mg/ 25 mg tablets

**This leaflet was last revised in 03/2022**