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## PACKAGE LEAFLET: INFORMATION FOR THE USER

### **Xenazine® 25** **25 mg Tablets** **Tetrabenazine**

Read all of this leaflet carefully before you start using 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 of the 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 Xenazine 25 is and what it is used for
2. What you need to know before you take Xenazine 25
3. How to take Xenazine 25
4. Possible side effects
5. How to store Xenazine 25
6. Contents of the pack and further information

#### **1. What Xenazine 25 is and what it is used for**

Xenazine 25 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 (called chorea).

Xenazine 25 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.

Xenazine 25 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.
- Xenazine 25 should only be given to you for treatment of tardive dyskinesia when symptoms are moderate to severe, disabling, and/or embarrassing in social situations.
- Xenazine 25 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 Xenazine 25**

Before you start taking Xenazine 25, please read the information given below. If you think that any of this information applies to you, or you are not sure, please tell your doctor, nurse or pharmacist.

#### **Do not take Xenazine 25:**

- If you are allergic (hypersensitive) to tetrabenazine or any of the other ingredients of the medicine (listed in section 6).
- If you are actively suicidal (feel like killing yourself).

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- 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 Xenazine 25:

- 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 behavior.
- 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 (listed in Other medicines and Xenazine 25) 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**

Xenazine 25 should normally not be used in children.

### **Other medicines and Xenazine 25**

Tell your doctor if you are taking, have recently taken, or might take any other medicines. Some medicines can cause problems if you take them with Xenazine 25.

These are:

- 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 Xenazine 25.

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- 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 Xenazine 25 with food and drink**

Drinking alcohol while you are taking Xenazine 25 may cause you to feel abnormally sleepy.

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

Xenazine 25 should not be taken during pregnancy, or when breast-feeding. If you are pregnant, think you might be pregnant or are planning to become pregnant, you should talk to your doctor who will explain the possible effect of Xenazine 25 on your unborn child.

When animals were tested, there was a delay in fertility seen. The effect on fertility in humans has not been tested. If you are concerned, ask your doctor for advice.

### **Driving and using machines**

Xenazine 25 may cause drowsiness and other side effects.

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

### **Xenazine 25 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 Xenazine 25**

Always take Xenazine 25 exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure. The dose required varies from person to person.

### **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 elderly patients.

### **Use in children**

If your doctor decides your child should take this medicine, your doctor will tell you how much to take.

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### **Taking Xenazine 25**

- The tablet can be divided into equal doses. Swallow the tablet or tablets 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 seven 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.

### **If you take more Xenazine 25 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 and drowsiness, redness/inflammation, and tremor.

### **If you forget to take Xenazine 25**

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 Xenazine 25**

Your doctor will decide when your treatment can be stopped. He may decide to gradually reduce the dose, although it may not be necessary. This is usually done so you avoid side effects that may arise as a result of suddenly stopping your medication.

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

## **4. Possible side effects**

Like all medicines, Xenazine 25 can cause side effects, although not everybody gets them.

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

#### Very Common (Likely to affect more than 1 in 10 people who take Xenazine 25)

- Xenazine 25 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 something called akathisia. If you feel like this, please contact your doctor.

#### Common (Likely to affect more than 1 in 100 people who take Xenazine 25)

- 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 something called parkinsonism. If you have any of these problems, please contact your doctor.

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Very Rare (Likely to affect less than 1 in 10,000 people who take Xenazine 25)

- 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 these symptoms, please contact your doctor straight away.
- If you have intentionally hurt yourself or if you have started to think about intentionally hurting yourself.

Frequency Unknown

- If you have a severe increase in blood pressure (hypertensive crisis).

**Please seek advice as soon as possible if you experience the following side effects:**

Very Common (Likely to affect more than 1 in 10 people who take Xenazine 25)

- Anxiety, confusion or restlessness.
- Movement disorders.
- Sleepiness.
- Problems with sleeping (insomnia).
- 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.
- Tiredness.
- Fall.

Common (Likely to affect more than 1 in 100 people who take Xenazine 25)

- Decreased appetite.
- Feeling agitated or irritable.
- Anxiety characterized by intrusive thoughts that produce uneasiness, apprehension, fear, or worry and by repetitive behaviours aimed at reducing the associated anxiety (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.

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Rare (Likely to affect less than 1 in 1,000 people who take Xenazine 25)

- Difficulty in swallowing.

Very Rare (Likely to affect less than 1 in 10,000 people who take Xenazine 25)

- Frequent infections such as fever, severe chills, sore throat, or mouth ulcers.
- Feeling aggressive or angry.
- Nervousness.
- Sleep disorder.
- Clumsiness and lack of coordination, affecting balance and manner of walking, limb or eye movements and/or speech.
- Tremor.
- Fast or irregular heartbeats (palpitations).
- Uncontrolled 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.
- 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 Xenazine 25 than you should**).

Frequency Unknown

- 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, 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 Xenazine 25**

- Keep this medicine out of the reach and sight of children.
- Do not use Xenazine 25 after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
- Do not store above 30°C.

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- REMEMBER this medicine is for you. Only a doctor can prescribe it for you. Never give it to others even if their symptoms are the same as yours.
  - Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. Contents of the pack and further information**

### **What Xenazine 25 contains**

- The active substance in the tablets is tetrabenazine. Each tablet contains 25 mg of tetrabenazine.
- The other ingredients are maize starch, lactose monohydrate, talc, magnesium stearate and the colorant iron oxide yellow (E172).

### **What Xenazine 25 looks like and contents of the pack**

Xenazine 25 tablets are round and yellowish-buff in colour. They have 'CL25' stamped on one side and a single scoreline on the other. The tablet can be divided into equal halves.

Xenazine 25 is supplied in bottles which each contains 112 tablets.

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

The holder of the Marketing Authorisation is  
Bausch Health Ireland Limited  
3013 Lake Drive  
Citywest Business Campus  
Dublin 24, D24PPT3  
Ireland

Xenazine 25 is manufactured by Astrea Fontaine, Rue des Près Potets, 21121 Fontaine-Lès-Dijon, France.

This product is distributed in the United Kingdom by Alliance Pharmaceuticals Ltd., Avonbridge House, Bath Road, Chippenham, Wiltshire SN15 2BB, UK.

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