

## Package leaflet: Information for the user

### Trimipramine 50mg Capsules

Trimipramine maleate

**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 Trimipramine Capsules are and what they are used for
2. What you need to know before you take Trimipramine Capsules
3. How to take Trimipramine Capsules
4. Possible side effects
5. How to store Trimipramine Capsules
6. Contents of the pack and other information

#### **1. What Trimipramine Capsules are and what they are used for**

Trimipramine 50mg Capsules contain trimipramine, which belongs to a group of medicines called antidepressants.

Trimipramine Capsules can be used **to treat depression**. They are especially useful for treating depression in people who also have problems sleeping, stress (anxiety) or feel irritable and restless (agitated).

#### **2. What you need to know before you take Trimipramine Capsules**

##### **Do not take Trimipramine Capsules if you:**

- are **allergic** to trimipramine or any of the other ingredients of the capsules (listed in Section 6 Further Information). See section 4 for the signs of an allergic reaction
- have had a **heart attack**
- have had any other **heart problems** including slow or uneven heart beat
- have severe **liver problems**
- have **mania** (signs include very high mood, energy and unusual behaviour)
- are **breast-feeding**

If you are not sure, talk to your doctor or pharmacist before taking trimipramine.

#### **Warnings and precautions**

##### **Thoughts of suicide and worsening of your depression or anxiety disorder**

If you are depressed and/or have anxiety disorders, you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

**If you have thoughts of harming or killing yourself at any time**, contact your doctor or go to a hospital straight away.

**You may find it helpful to tell a relative or close friend** that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

If you have **diabetes** or are at risk of getting diabetes, your doctor may do blood tests to monitor your blood sugar levels.

**Check with your doctor or pharmacist before taking this medicine if you:**

- are **elderly**
- have an **enlarged prostate** gland
- have **glaucoma** (painful eyes with blurred vision)
- have or have ever had **fits** or seizures
- have **thyroid** problems

The use of Buprenorphine together with trimipramine can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Trimipramine").

If you are not sure, talk to your doctor or pharmacist before taking trimipramine.

**Other medicines and Trimipramine Capsules**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because trimipramine can affect the way some other medicines work and some medicines can affect the way trimipramine works.

**In particular, tell your doctor if you are taking any of the following medicines:**

- MAOI (MonoAmine Oxidase Inhibitors) medicines such as tranylcypromine, phenelzine and isocarboxazid (for **Parkinson's disease**), or you have taken them in the last 2 weeks
- **Sedatives** (such as tranquilizers or sleeping pills)
- Medicines used to treat **high blood pressure**
- Adrenaline, noradrenaline, ephedrine or isoprenaline – used in an emergency
- Phenylephrine or phenylpropanolamine – found in **cold and flu** medicines
- Medicines used for **chest pain** (angina) or **high blood pressure** such as diltiazem, verapamil, clonidine, digitalis
- Medicines used for **depression** (SSRIs such as citalopram, paroxetine, fluoxetine) tricyclic antidepressants and triptan derivatives, lithium and St John's Wort (a herbal remedy)
- **Painkillers** such as tramadol
- **Buprenorphine/opioids**. These medicines may interact with trimipramine and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.
- Macrolide **antibiotics**, **antifungals** or fluoroquinolones.

**Anaesthetics**

If you are going to have an anaesthetic (for an operation), tell your doctor or dentist that you are taking trimipramine.

**Taking trimipramine with alcohol**

You should avoid drinking alcohol while taking trimipramine.

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

#### **Pregnancy**

Trimipramine should not be used during pregnancy especially during the first and last trimesters unless there are compelling reasons.

#### **Breast-feeding**

Trimipramine should not be used during breast-feeding.

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.

### **Driving and using machines**

Trimipramine may make you feel sleepy or less alert. If this happens, do not drive or use any tools or machines.

### **Trimipramine Capsules contain sodium**

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

## **3. How to take Trimipramine Capsules**

Always take trimipramine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

### **Taking this medicine**

- Take this medicine by mouth
- Swallow the capsules whole with a drink of water
- If you have been told to take trimipramine only once each day then you should take it before going to bed
- It may take 7 to 10 days before you feel the full benefit of the medicine
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself but ask your doctor

### **How much to take**

#### Adults

- The usual starting dose is 50mg to 75mg each day.
- Your doctor may then increase the dose to 150mg or 300mg each day depending on your condition
- Once you start to feel better, the usual daily dose then stays the same at 75mg to 150mg each day

#### Elderly

- The usual starting dose is 10mg to 25mg three times each day
- Your doctor will then increase this slowly
- Once you start to feel better, the usual daily dose stays the same at 35mg to 75mg each day

#### *Children*

This medicine should not be used in children as the safety and efficacy of Trimipramine in children have not yet been established.

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

Tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. The following effects may happen if you take too many capsules: fits (seizures), collapse and falling into a coma.

### **If you forget to take Trimipramine**

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

### **If you stop taking Trimipramine**

Keep taking trimipramine until your doctor tells you to stop. Do not stop taking trimipramine just because you feel better. This is because your illness may come back. When your doctor tells you to stop taking these capsules, he/she will help you stop taking them gradually.

Stopping your medicine too quickly could cause sleep problems, feeling irritable and sweating more than usual.

## **4. Possible side effects**

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

### **Stop taking trimipramine and see a doctor or go to a hospital straight away if:**

- You get **swelling** of the hands, feet, ankles, face, lips or throat which may cause **difficulty swallowing or breathing**, itching of the skin and nettle rash. This may mean you are having an allergic reaction to trimipramine.

### **Talk to your doctor straight away if you notice any of the following side-effects:**

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

- Painful erection of the penis, unrelated to sexual activity, that will not go away (priapism)
- Feeling drowsy or sleepy
- Constipation
- Dry mouth
- Tremor (shaking)
- Blurred vision
- Rapid heartbeat
- Sweating more than usual
- Feeling dizzy or light-headed on standing or sitting up quickly (postural hypotension)
- Sexual problems
- Delay when starting to pass water (urine)
- Skin rash

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

- Yellowing of the eyes or skin. This could be a liver problem (such as jaundice)
- Overactive behaviour or thoughts (mania or hypomania)
- Numbness or weakness in the arms and legs (peripheral neuropathy)
- Feeling that someone is 'out to get you'
- Getting infections more easily than usual. This could be because of a blood disorder (agranulocytosis)
- Convulsions/fits
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia)

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

- Increased thirst and passing water (urine) more often than normal. You may also feel tired and hungry. This could be due to high blood sugar levels or a condition called

diabetes

- An uneven or fast heartbeat
- An increased risk of bone fractures has been observed in patients taking this kind of medicine.

### **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](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 Trimipramine Capsules**

Keep this medicine out of the sight and reach of children.

Do not use Trimipramine Capsules after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

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

Store in the original package in order to protect from moisture.

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 other information**

### **What Trimipramine Capsules contains**

- Each Trimipramine 50mg Capsules contains 69.75mg of the active substance, trimipramine maleate, equivalent to 50mg of trimipramine
- The other ingredients are microcrystalline cellulose (E460), colloidal anhydrous silica, croscarmellose Sodium, pre-gelatinised Starch and magnesium Stearate
- The capsule shell contains titanium dioxide (E171), indigotine (E132), iron oxide yellow (E172) and gelatin
- The printing ink contains shellac, iron oxide black (E172) and potassium hydroxide

### **What Trimipramine Capsules look like and contents of the pack**

Trimipramine 50mg Capsules are hard gelatin capsule approximately 19.20 x 6.93 mm in size with white opaque body imprinted with “301” in black ink and green cap imprinted with Glenmark logo “G” in black ink, filled with white to pale yellow powder.

They are supplied in blister packs of 28 capsules.

## **Marketing Authorisation Holder and Manufacturer**

### **Marketing Authorisation Holder**

Glenmark Pharmaceuticals Europe Limited  
Laxmi House, 2B Draycott Avenue, Kenton, Middlesex  
HA3 0BU  
United Kingdom

**Manufacturer**

Glenmark Pharmaceuticals Europe Limited  
Building 2, Croxley Green Business Park, Croxley Green, Hertfordshire  
WD18 8YA, United Kingdom

Glenmark Pharmaceuticals s.r.o.  
Fibichova 143  
56617 Vysoke Myto  
Czech Republic

**This leaflet was last revised in 05/2021.**