

Package leaflet: Information for the patient
Trimipramine 10mg and 25mg Tablets
Trimipramine

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Trimipramine Tablets are and what they are used for

The name of your medicine is Trimipramine 10mg or 25mg Tablets (called trimipramine throughout this leaflet). Trimipramine belongs to a group of medicines called antidepressants and can be used to treat depression. In particular it is used to treat depression in people who also have the following symptoms - problems sleeping, anxiety or are feeling irritable and restless (agitation).

2. What you need to know before you take Trimipramine Tablets

Do not take Trimipramine Tablets:

- If you are allergic to trimipramine maleate or any of the other ingredients of this medicine (listed in section 6) (Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue)
- If you have had a heart attack
- If you have any other heart problems including slow or uneven heartbeat
- If you have severe liver problems
- If you have mania (signs include very high mood, energy and unusual behaviour)
- If you are breast-feeding.

Do not take trimipramine if the above apply to you. If you are not sure, talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Trimipramine Tablets

- If you are elderly
- If you have an enlarged prostate gland
- If you have glaucoma (an increased pressure in the eye)
- If you have a history of epilepsy
- If you have thyroid problems

The use of buprenorphine/ naloxone together with Trimipramine Tablets can lead to serotonin syndrome, a potentially life-threatening condition (see Other medicines and Trimipramine Tablets).

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.

Other medicines and Trimipramine Tablets

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

This is because trimipramine can affect the way some other medicines work.

Also some medicines can affect the way trimipramine works.

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

- MAOI (Mono Amine Oxidase Inhibitors) medicines such as tranylcypromine, phenelzine and isocarboxazid (for depression) or selegiline (for Parkinson's disease). **Tell your doctor or pharmacist if you are taking them now or have taken them in the last 2 weeks**
- Sedatives such as tranquilizers or sleeping pills
- Medicines used to treat high blood pressure such as guanethidine, debrisoquine and bethanidine
- Adrenaline, noradrenaline, ephedrine or isoprenaline – used in an emergency
- Medicines, including some cough and cold medicines, containing ephedrine, pseudoephedrine or adrenaline
- 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) tricyclics and triptan derivatives, lithium, St John's Wort
- Pain killers such as tramadol
- Macrolide antibiotics, antifungals or fluoroquinolones
- Hypokalemic diuretics, stimulant laxatives and beta-blockers.

Some medicines may increase the side effects of Trimipramine Tablets and may sometimes cause very serious reactions.

Do not take any other medicines whilst taking Trimipramine Tablets without first talking to your doctor, especially:

- buprenorphine/ naloxone (used to treat opioid overdose). These medicines may interact with Trimipramine Tablets 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.

Anaesthetics

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

Trimipramine Tablets with food, drink and alcohol

You should avoid drinking alcohol while taking trimipramine. This is because trimipramine can change the way alcohol affects you.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take and tell your doctor before taking trimipramine if you are:

- Pregnant, might become pregnant, or think you may be pregnant.
- Breast-feeding

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.

Information on Lactose and Sodium content

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

3. How to take Trimipramine Tablets

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

The dose of trimipramine will depend on your needs and the illness being treated.

The recommended dose is:

Adults

- The usual starting dose of trimipramine is 50mg to 75mg each day
- Your doctor may then increase the dose to between 150mg and 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 of trimipramine 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 then stays the same at 35mg to 75mg each day.

Use in children and adolescents

Do not give trimipramine to children.

Method of administration

- Swallow the tablets whole with a drink of water
- If Trimipramine Tablets is taken only once each day, you should take it before going to bed
- Your doctor may decide you should take Trimipramine Tablets more than once each day
- It may take 7 to 10 days before you feel the full benefit of the medicine.

If you take more Trimipramine Tablets than you should

If you take more trimipramine than you should, tell a doctor or go to a hospital casualty department straight away. Take the carton and any tablets left with you. This is so the doctor knows what you have taken. The following effects may happen convulsions, collapse and falling into a coma.

If you forget to take Trimipramine Tablets

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 Tablets

- 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 tablets he/she will help you stop taking them gradually.
- Stopping your medicine too quickly could cause sleep problems, leave you feeling more irritable than usual and cause you to sweat more than usual.

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.

Stop taking Trimipramine Tablets 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. You could also notice an itchy, lumpy rash known as urticaria or hives. This may mean you are having an allergic reaction to Trimipramine.
- You have thoughts of harming or killing yourself at any time.

Talk to your doctor straight away if you notice the following side-effects:

- Painful erection of the penis, unrelated to sexual activity, that will not go away (priapism)
- 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 unable to trust people or things, for no reason. This could be a sign of a mental problem called paranoia
- Getting infections more easily than usual. This could be because of a blood disorder (low white blood cell numbers)
- Fits (seizures)
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia)
- 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

Tell your doctor or pharmacist if any of the following side effects get serious or last longer than a few days:

Common: may affect up to 1 in 10 people

- 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
- Sexual problems
- Delay when starting to pass water (urine)
- Skin rash

An increased risk of bone fractures has been observed in patients taking this type of medicines.

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 website: 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 tablets

- Keep out of the sight and reach of children.
- Do not store above 25°C. Store in the original packaging.
- Do not use this medicine after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines no longer required. These measures will help to protect the environment.

6. Content of the pack and other information

What trimipramine contains

Each Trimipramine 10mg Tablet contains 13.948mg of trimipramine maleate, equivalent to 10mg of trimipramine.

Each Trimipramine 25mg Tablet contains 34.87mg of trimipramine maleate, equivalent to 25mg of trimipramine.

The other ingredients are lactose monohydrate, sodium lauryl sulphate, maize starch, calcium hydrogen phosphate dehydrate, magnesium stearate

What trimipramine looks like and contents of the pack

Trimipramine 10mg and 25mg Tablets are white coloured round tablets.

Trimipramine 10mg and 25mg tablets are supplied in blister packs of 28 and 84 tablets.

Marketing Authorisation Holder

Focus Pharmaceuticals Limited
Dashwood House,
69 Old Broad Street,
London,
EC2M 1QS,
United Kingdom

Manufacturer

Mercury Pharmaceuticals Ltd, Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom

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