

Clomipramine 10	Film-coated tablets 10 mg
Clomipramine 25	Film-coated tablets 25 mg

What you need to know about Clomipramine tablets

Please read this leaflet carefully before you start to use your medicine. It contains important information.

What's in your medicine?

Clomipramine tablets contain clomipramine hydrochloride. This is one of a group of medicines called antidepressants. The tablets come in three strengths containing 10 and 25mg clomipramine.

Clomipramine tablets also contain the following inactive ingredients: Microcrystalline Cellulose, Povidone, Maize Starch, Lactose, Sodium Starch Glycolate, Colloidal Silicon Dioxide, Magnesium Stearate, Talc, Hypromellose, Titanium Dioxide, Macrogol 400, Red Ferric Oxide E172.

Clomipramine 10: This product is available in pack-sizes of 20, 100 and 1000 tablets.

Clomipramine 25: This product is available in pack-sizes of 20, 100 and 1000 tablets.

Not all pack-sizes may be marketed.

Marketing Licence Holder & Manufacturer:

Remedica Ltd, Limassol Industrial Estate, Limassol, Cyprus, EU.

How does your medicine work?

Clomipramine is a tricyclic antidepressant. It is thought to work by increasing the amount or prolonging the effect of chemical "messengers" in the brain.

What this medicine is used for

Clomipramine is used to treat depression, obsessions and phobias, and muscular weakness (cataplexy) associated with recurrent attacks of extreme sleepiness (narcolepsy).

Before taking your medicine, ask yourself the following questions:

- Are you allergic to clomipramine or to any of the other ingredients of Clomipramine?
- Have you ever had a rash or other possible allergic reaction whilst taking any other antidepressants?
- Are you pregnant or trying to become pregnant?
- Are you breast-feeding?
- Have you had a heart attack within the last 3 months?
- Do you suffer from any serious heart or liver disease?
- Do you suffer from any mental illness other than depression, obsessions or phobias?
- Are you thinking about suicide?
- Do you suffer from glaucoma (increased eye pressure)?
- Do you have difficulty in passing urine?
- Are you taking, or have you taken within the last 3 weeks, any other medicines for depression (particularly monoamine oxidase inhibitors [MAOIs])?
- Do you have intolerance to some sugars?
- If the answer to any of these questions is YES, do not take the Clomipramine tablets without talking to your doctor again.
- Do you suffer from epilepsy (fits)?
- Do you have an overactive thyroid gland?
- Have you been troubled by severe constipation over a long period of time?
- Do you have a tumour (cancer) of the adrenal gland (such as pheochromocytoma or neuroblastoma)?
- Do you have low blood pressure?
- Do you wear contact lenses?

If the answer to any of these questions is YES, tell your doctor or pharmacist.

Can you take Clomipramine tablets with other medicines?

You should tell your doctor or pharmacist if you are taking any of the following medicines:

Medicines for mental illnesses (including fluoxetine, fluvoxamine, thioridazine), medicines for high blood pressure or heart disorders, anticoagulants (blood thinning tablets like warfarin), medicines for Parkinson's Disease, a medicine called terbinafine (used orally to treat skin, hair or nail infections due to fungus), cold remedies or hay fever preparations, carbamazepine and phenytoin (for epilepsy), cimetidine, methylphenidate, barbiturates, nicotine, atropine, estrogens (e.g. contraceptive pill or hormone replacement therapy). You should also tell your doctor or pharmacist if you are taking any other medicines that your doctor does not know about, including any that you have bought for yourself without a prescription. These medicines may interact with Clomipramine so it may be necessary to change the dose or stop one of the medicines.

Is there anything else you need to know before taking your medicine?

Be careful when drinking alcohol – it may affect you more than usual.

If you feel dizzy or have blurred vision when you start to take Clomipramine, do not drive or work with machinery until this effect has worn off.

Tell your doctor or dentist if you are planning to have an operation of any kind, as Clomipramine may interact with local or general anaesthetics.

Regular dental check-ups are advisable if you are taking Clomipramine for a long time, as this medicine can cause dryness of the mouth, which may increase the chance of tooth decay.

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 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 behavior.

How to take your medicine

It is important to take your medicine as instructed by your doctor.

Clomipramine tablets are not recommended for children.

The usual dosages are as follows:

For depression:

10 mg–150mg daily

For obsessions and phobias:

10 mg–150 mg daily

For cataplexy:

10 mg–75 mg daily

The medicine may be taken as one dose at night, or split into several smaller doses and taken throughout the day. Elderly patients often need a lower dose. Your doctor will tell you about this.

If you are not sure how many Clomipramine tablets to take, ask your doctor or pharmacist.

• Swallow your Clomipramine tablets whole with a drink of water

• Keep taking your medicine until your doctor tells you to stop. Do not stop because you do not feel any better. This medicine may take up to 4 weeks to work.

What if you miss a dose?

If you forget to take a dose, take the next dose at the usual time. DO NOT take a double dose.

What if you take too many?

If you accidentally take too many Clomipramine tablets, tell your doctor at once or contact your nearest hospital casualty department. Take your medicine with you.

Information for families and caregivers

You should monitor whether your depressed patient shows signs of behavioral changes such as unusual anxiety, restlessness, sleeping problems, irritability, aggressiveness, over excitement or other unusual changes in behavior, worsening of depression or thinking about suicide. You should report any such symptoms to the patient's doctor, especially if they are severe, abrupt in onset, or were not part of the patient's presenting symptoms before. You should evaluate the emergence of such symptoms on a day-to-day basis, especially early during antidepressant treatment and when the dose is increased or decreased since changes may be abrupt. Symptoms such as these may be associated with an increased risk for suicidal thinking and behavior and indicate a need for very close monitoring and possibly changes in medication.

After taking your medicine

Clomipramine tablets sometimes cause unwanted effects in some people. If you get any of the following, tell your doctor:

- A nervous system disorder characterized by muscle stiffness, high fever and impaired consciousness;
- Skin rash or itching for the first time
- Any yellowing of your skin or the whites of your eyes
- Persistent sore throat, fever or frequent infections
- Unexplained bruising or bruising more easily
- Light-headedness when you stand up
- Mood changes, including increased anxiety or agitation
- Fits
- Cough, shortness of breath or breathing difficulties
- Other effects, which may occur, include:
- Headaches, dizziness
- Upset stomach, diarrhea, constipation
- Weight gain, change in appetite
- Dry mouth, changes in taste
- Shakiness of the hands
- Increased sweating or hot flushes
- Disturbance of vision or speech
- Yawning, tinnitus (ringing in the ears)
- Feeling tired, sleepy, slightly confused or disorientated
- Sleep disturbances, nightmares, hallucinations, delirium
- Impaired memory and concentration
- Difficulty in passing urine
- Unusually fast heartbeat or palpitations
- Increased sensitivity of the skin to sunlight
- Sexual disturbances, breast changes
- Numbness or tingling in the arms or legs, muscle weakness, movement disorder
- Oedema (swelling of the ankles), hair loss
- Raised blood pressure

These effects are often mild and may wear off after a few days' treatment. If they are severe or last for more than a few days, tell your doctor. Also, if your medicine upsets you in any other way, tell your doctor.

An increased risk of bone fractures has been observed in patients taking these types of medicines.

Expiry date of the medicine:

Shown on the inner and outer packaging. In case the expiry date has lapsed, do not use.

Special precautions for storage of the product:

Keep below 25°C, away from light and moisture and out of the reach of children.

REMEMBER: This medicine is for you. Only a doctor can prescribe it for you. Never give it to somebody else. It may harm them even if they have the same symptoms

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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 behavior in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

- Weight gain, change in appetite

- Dry mouth, changes in taste
- Shakiness of the hands
- Increased sweating or hot flushes
- Disturbance of vision or speech
- Yawning, tinnitus (ringing in the ears)
- Feeling tired, sleepy, slightly confused or disorientated
- Sleep disturbances, nightmares, hallucinations, delirium
- Impaired memory and concentration
- Difficulty in passing urine
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