

Package leaflet: Information for the patient

**Clomipramine 10 mg Capsules, Hard
Clomipramine 25 mg Capsules, Hard
Clomipramine 50 mg Capsules, Hard**

clomipramine hydrochloride

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 Clomipramine is and what it is used for.
2. What you need to know before you take Clomipramine.
3. How to take Clomipramine.
4. Possible side effects.
5. How to store Clomipramine.
6. Contents of the pack and other information.

1. What Clomipramine is and what it is used for

Clomipramine is available as capsules in three different strengths.

Clomipramine belongs to a group of medicines called tricyclic antidepressants. Clomipramine is believed to work by increasing the levels of two naturally occurring chemicals within the brain, noradrenaline and 5-hydroxytryptamine (also called serotonin).

Clomipramine is used to treat depression (especially if you also need to be sedated), obsessions and phobias (irrational fears). It is also used along with other medications to treat cataplexy. Cataplexy is a disorder which causes muscle weakness and symptoms such as sagging jaw, drooping head and weakness at the knees. Attacks of cataplexy are triggered by strong emotions. Cataplexy often affects people who have narcolepsy (a sleep disorder).

This medicine is for adults only.

2. What you need to know before you take Clomipramine

Do NOT take Clomipramine if you:

- are allergic to clomipramine or any of the other ingredients of this medicine (listed in section 6)
- have ever had a rash or other allergic reaction to any other antidepressants
- have had a heart attack within the last 3 months
- have problems with your heart beat
- have any serious liver disease
- have a mental health condition called mania
- have glaucoma (increased eye pressure)
- have difficulty in passing urine
- are taking, or within the last 3 weeks have taken medicines for depression called monoamine oxidase inhibitors (MAOI)
- are taking medicines called selective, reversible monoamine oxidase-A (MAO-A) inhibitors such as moclobemide

If you are unsure if any of the above applies to you, please talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking Clomipramine if you:

- have ever had suicidal thoughts
- suffer from epilepsy (fits)
- have had a head injury or have suffered brain damage
- are going to have electric shock therapy (ECT)
- have other problems with your heart
- have been told you have a low level of potassium in your blood (hypokalaemia). The doctor will need to treat this before you start taking clomipramine
- have kidney disease
- suffer from schizophrenia or other mental health conditions
- have a blood disorder
- have an overactive thyroid gland
- have had severe constipation for a long time
- have a tumour (cancer) of the adrenal gland (such as phaeochromocytoma or neuroblastoma)
- liver disease
- have low blood pressure
- wear contact lenses
- are elderly
- The use of Buprenorphine together with Clomipramine can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Clomipramine").

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 young adults (less than 25 years old) with mental health 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.

Information for families, and caregivers

You should monitor whether your depressed patient shows signs of behavioural changes such as unusual anxiety, restlessness, sleeping problems, irritability, aggressiveness, over-excitedness or other unusual changes in behaviour, worsening of depression or thinking about suicide. You should report any such symptoms to the patient's doctor, especially if they are severe, start suddenly, or were not part of the patient's presenting symptoms before. You should evaluate the emergence of such symptoms on a day-day basis, especially during anti-depressant 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 behaviour and indicate a need for very close monitoring and possibly changes in medication.

Tell your doctor, dentist or hospital staff you are taking Clomipramine if you are to have surgery (including dental procedures), as the dose of Clomipramine may need to be reduced or stopped before you have an anaesthetic.

While you are taking Clomipramine, especially if you take this medicine for a long time your doctor may want to monitor you by doing blood tests and other tests to check your heart and liver function. You should also have regular dental check-ups, as Clomipramine may cause dryness of the mouth which can increase the chance of tooth decay.

Other medicines and Clomipramine

Tell your doctor if you are taking, have recently taken or might take any other medicines. Some medicines may increase the side effects of Clomipramine and may sometimes cause very serious reactions. Do not take any other medicines whilst taking Clomipramine without first talking to your doctor, especially:

- medicines for depression, particularly MAOIs (see section "Do not take" above) e.g. tranylcypromine, phenelzine, moclobemide; SSRIs e.g. fluoxetine (or have taken within the last 3 weeks), fluvoxamine, paroxetine, sertraline; SNaRIs e.g. venlafaxine; tricyclic and tetracyclic antidepressants e.g. amitriptyline, dothiepin, maprotiline
- diuretics, also known as 'water tablets', e.g. bendroflumethiazide, furosemide
- anaesthetics, used for the temporary loss of bodily sensation
- antihistamines e.g. terfenadine
- medicines for other mental health conditions such as schizophrenia or manic depression e.g. thioridazine, lithium, clozapine, pimozide, benzodiazepines e.g. alprazolam
- medicines for high blood pressure e.g. guanethidine, betanidine, reserpine, clonidine or alpha methyl dopa or norepinephrine
- norepinephrine (noradrenaline), used to treat low blood pressure
- medicines to treat heart disorders, particularly those used to treat an abnormal heart rhythm, e.g. disopyramide, procainamide, epinephrine (adrenaline), isoprenaline, amiodarone, quinidine, diltiazem and verapamil
- beta-blockers e.g. atenolol, sotalol
- anticoagulants (blood thinning tablets) e.g. warfarin
- aspirin and similar pain killing non-steroidal anti-inflammatory drugs (NSAIDs)
- medicines for Parkinson's Disease, e.g. levodopa, biperiden, entacapone or selegiline
- nicotine e.g. if you smoke or are using nicotine replacement therapy
- anticonvulsants, used to stop seizures or fits e.g. barbiturates such as phenobarbital, phenytoin, carbamazepine or valproate
- decongestants used for colds and flu such as ephedrine, phenylephrine or phenylpropanolamine
- cimetidine, used to treat stomach ulcers or heartburn
- methylphenidate used to treat for ADHD
- rifampicin, used to treat some infections including tuberculosis (TB)
- quinine, for cramp or malaria treatment
- strong painkillers such as tramadol, nefopam, morphine or morphine related substances e.g. codeine, dihydrocodeine
- drugs of abuse including Ecstasy
- atropine or similar medicines (including eye drops)
- medicines containing oestrogens e.g. contraceptive pill or hormone replacement therapy
- medicines called protease inhibitors, used to treat Human Immunodeficiency Virus (HIV) e.g. ritonavir, indinavir
- terbinafine, used orally to treat skin, hair or nail infections due to fungus
- colestipol, cholestyramine, used to treat high cholesterol levels
- St. John's wort (*Hypericum perforatum*), a herbal product used to treat depression and other conditions
- disulfiram, used to help you stop drinking alcohol
- altretamine, used to treat cancer
- baclofen, used in the treatment of multiple sclerosis and spinal damage
- pentamidine, an antibiotic used to treat pneumonia
- levacetylmethadol, used to treat addiction to opioid drugs such as heroin.
- **buprenorphine/ opioids (used to treat opioid overdose)**. These medicines may interact with Clomipramine 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.

Clomipramine with food, drink and alcohol

Take care when eating grapefruit, or drinking grapefruit juice or cranberry juice as this may increase your chance of experiencing side effects. Be careful when drinking alcohol - it may affect you more than usual.

Pregnancy and breast-feeding

Clomipramine should not be taken if you are pregnant unless your doctor has told you to do so.

Clomipramine may harm your unborn child.

Clomipramine may reach your baby through the breast milk. Therefore, you should not take Clomipramine if you are 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.

Driving and using machines

If you feel dizzy, tired, have blurred vision, have difficulty concentrating, or have other effects such as confusion, disorientation or your depression gets worse when you start to take Clomipramine do not drive or work with machinery until these effects have worn off.

Alcohol and other medicines may make these side effects worse (see "Other medicines and Clomipramine")

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
 - o The medicine has been prescribed to treat a medical or dental problem and
 - o You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - o It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Clomipramine capsules contains 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.

Clomipramine 10 mg capsules contain Sunset yellow (E110)

This may cause allergic reactions.

3. How to take Clomipramine

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

If you have low blood potassium (hypokalaemia) your doctor will treat this before you can start treatment.



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Sign-offs							
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