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 methyldopa 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
Available data do not suggest an increased risk of overall birth defects. However, some data from health registries suggest an increased risk of heart malformations when clomipramine was used during the first three months of pregnancy (2 cases in 100 pregnancies) compared to the general population (1 case in 100 pregnancies).

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:
  - The medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - 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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reading direction
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VIATRIS

Description	Clomipramine_10mg_25mg_50mg_28		
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Superseded Affiliate Item Code	4043233	Vendor Job No.	123090648/0020
TrackWise Job No	4157172	Artwork Proof No.	1
MA No.	PL 04569/0229, PL 04569/0230, PL 04569/0231	Client Market	United Kingdom
Supplier SAP No.	N/A	Market Barcode Info	N/A
New Supplier Code	51767785	3D Render ID	N/A
Superseded Supplier Code	51766080	GTIN/PC	N/A

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Non-Print Colours	Technical Info		
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Dimensions	160 x 600 mm	Min Text Size used	9 pt

The recommended dose is:

- **For depression** a starting dose of 10 mg which can be increased to find a dose that works for you. This is normally 30 - 150 mg daily or up to a maximum of 250 mg daily for severe conditions.
- **For obsessions and phobias** a starting dose of 25 mg which can be increased to 100 - 150 mg daily.
- **For cataplexy** a starting dose of 10 mg which can be increased to a maximum of 75 mg daily.

Elderly patients often need a lower dose because they are more likely to experience side effects. The maximum dose for elderly patients is 75 mg daily. Your doctor will tell you about this.

Do not stop taking Clomipramine suddenly because this may cause withdrawal side effects. If the decision is made by your doctor to discontinue treatment, the dose you receive will be cut down gradually to prevent the development of withdrawal symptoms. You may get these side effects if you stop taking Clomipramine suddenly: feeling or being sick, stomach ache, diarrhoea, headache, difficulty sleeping, nervousness or anxiety.

Use in children and adolescents (0 to 17 years):
Clomipramine is **not** recommended in children and adolescents.

Method of administration
Swallow your Clomipramine capsules whole with a drink of water.

The medicine may be taken as one dose at night, or split into several smaller doses and taken throughout the day. Your doctor will tell you what to do.

Duration of treatment
Treatment is often long-term. Once an effective dose is reached, you should continue to take this medicine until your doctor tells you to stop.

If you take more Clomipramine than you should
Your heart and nervous system will be affected. Contact your doctor or nearest hospital emergency department **immediately**. Take the container and any remaining capsules with you.

You may have the following signs of illness: drowsiness, stupor (when you are unable to move but still conscious) coma (unconscious), ataxia (uncoordinated muscle movement), restlessness, agitation, enhanced reflexes, muscle stiffness, irregular muscle contractions, twisting and writhing movements of the hands and feet, convulsions (fits). You may also have signs of so-called "Serotonin Syndrome" (very high blood pressure, very high fever, muscle twitching, confusion and coma). Other signs include: rapid or irregular heartbeat, sudden chest pain (angina) and in very rare cases heart attack, fever, being sick, abnormally dilated pupil, sweating, low blood pressure or a severe drop in blood pressure, shortness of breath, blue skin, and a decrease or absence of urine production.

If you forget to take Clomipramine
If you miss a dose, take the next dose at the usual time. Then go on as before. **DO NOT** take a double dose to make up for a forgotten dose.

If you stop taking Clomipramine
Speak to your doctor first before stopping this medicine. Your doctor will tell you how to gradually reduce your medication. This will help avoid unwanted side effects such as feeling sick, being sick, stomach pain, diarrhoea, sleeplessness, headache, feeling nervous or anxious.

If you suffer from cataplexy, your symptoms may get worse when you stop the medicine suddenly.

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.

Some side effects can be serious
Stop taking Clomipramine and tell your doctor immediately or go to your nearest hospital emergency department if you notice the following:

Common (may affect up to 1 in 10 people)
- changes in your mood or behaviour such as feeling unusually happy, excited (delirious), irritable, confused, seeing or hearing things that aren't there (hallucinations) or changes in your perception of reality (depersonalisation).
- difficulty or inability to pass urine

Uncommon (may affect up to 1 in 100 people)
- convulsions (fits)

Very rare (may affect up to 1 in 10,000 people)
- rash, changes in blood pressure, swelling of the hands, face, tongue, neck or throat and increased fluid in tissues, an increased heart rate, difficulty breathing and collapse. These may all be the signs of a severe allergic reaction
- a high temperature and sweating with rigid muscles and confusion or agitation, or if you experience jerky muscle movements which you can't control. These may be the symptoms of a serious condition known as neuroleptic malignant syndrome
- low numbers of white blood cells, leading to frequent infections, such as fever, chills, sore throat or mouth ulcers
- changes to your eyesight that may be due to high pressure in the eye (known as glaucoma)
- very high fever or heatstroke
- disease of the liver (known as hepatitis), this may result in jaundice. You may feel sick, be sick, generally feel unwell, lose your appetite, have a fever, yellowing of the skin or whites of the eyes, light coloured stools and dark-coloured urine
- problems with how your heart beats. You may have shortness of breath, irregular heart beat and fainting (especially if you have low potassium levels in your blood)
- a lower than normal level of sodium in the blood, which may make you feel weak and confused with aching of muscles. This may be due to inappropriate ADH secretion, a hormone that causes the body to retain water and dilute the blood, reducing the amount of sodium.

Not known (frequency cannot be estimated from the available data)
- thoughts of suicide or self-harm (see section 2 for more information)
- breakdown of muscle, causing muscle pain, weakness or tenderness accompanied by dark urine (rhabdomyolysis)
- serotonin syndrome (caused by an increase in naturally occurring messenger, serotonin, in the brain; symptoms include agitation, confusion, diarrhoea, high temperature, increased blood pressure, excessive sweating and rapid heartbeat)
- Damage to the heart muscle (cardiomyopathy)
- Heart failure

Other side effects that you may experience

Very common (may affect more than 1 in 10 people)
- increase in appetite, weight gain
- headaches, dizziness, feeling sick (nausea), constipation, dry mouth, increased sweating
- shaking (particularly the hands), problems with your eye sight including blurred vision, feeling tired or sleepy
- problems with either your sex drive or getting or maintaining an erection
- muscle twitching, restlessness
- changes in the amount of sugar in the blood
- changes to the amount of urine you produce or frequency of urination.

Common (may affect up to 1 in 10 people)
- reduced appetite
- stomach problems
- being sick
- diarrhoea
- fast heart rate, which you may feel as a racing or thumping in the chest (palpitations), light-headedness when standing up (due to low blood pressure)
- increased anxiety
- hot flushes
- enlarged pupils
- problems with your speech
- yawning
- feeling confused or aggressive
- feeling disorientated or agitated
- sleep disturbances
- nightmares
- worsening of existing depression
- impaired memory or concentration
- increased sensitivity of the skin to sunlight
- rash, hives or itching
- breast enlargement, spontaneous flow of milk from the breast
- women may not be able to orgasm
- minor changes to your electrocardiogram (ECG) may show up if your heart is tested
- numbness or tingling in the arms and legs
- movement disorder
- changes in liver function tests
- changes to sense of taste
- ringing in the ears (tinnitus).

Uncommon (may affect up to 1 in 100 people)
- clumsiness and lack of coordination, affecting balance and walking, limb or eye movements
- increased blood pressure
- irregular heartbeats.

Rare (may affect up to 1 in 1,000 people)
- vaginal bleeding.

Very rare (may affect up to 1 in 10,000 people)
- fluid retention or generalised swelling
- hair loss
- swelling of the lungs which can cause flu-like effects such as coughing, chest tightness, chills wheezing and difficulty breathing.
- unexplained or easily bruising under the skin or increased bleeding if you are cut or injured (due to low platelet levels in your blood)
- blue or purplish spots on the skin (ecchymosis)
- bleeding in the skin causing purple patches
- abnormal reading of the electrical activity of the brain (as seen in an electroencephalogram)

Not known (frequency cannot be estimated from the available data)
- feeling of inner restlessness and a compelling need to be in constant motion
- repetitive, involuntary movements
- inability to ejaculate or a delay in ejaculation
- increase in prolactin (a hormone) level in the blood.

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

If you are elderly you may be more likely to suffer from agitation and postural hypotension. Mental disorders such as confusion, disorientation and hallucinations (seeing or hearing things that are not there) are also more likely, especially at night, and especially if you have Parkinson's disease. These side effects should disappear a few days after you stop taking Clomipramine.

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, website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Clomipramine

Store Clomipramine capsules below 25°C in a dry place.

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

Do not use this medicine after the expiry date, which is stated on the pack or bottle. The expiry date refers to the last day of that month.

If your doctor tells you to stop taking Clomipramine please take any unused medicine back to your pharmacist to be destroyed. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Clomipramine contains

The active substance is clomipramine hydrochloride. Each 10 mg capsule contains 10 mg clomipramine hydrochloride. Each 25 mg capsule contains 25 mg clomipramine hydrochloride. Each 50 mg capsule contains 50 mg clomipramine hydrochloride.

The other ingredients are lactose monohydrate (see section 2 'Clomipramine contains lactose'), maize starch dried, purified talc, silica, colloidal anhydrous and magnesium stearate. The shell of each strength of capsule also contains gelatin, iron oxide red (E172) and titanium dioxide (E171). The 10 mg capsule shell also contains Sunset yellow (E110) (see section 2 'Clomipramine contains Sunset yellow') and Quinoline yellow (E104). The 25 mg capsule shell also contains iron oxide yellow (E172) and erythrosine (E127). The 50 mg capsule shell also contains Indigo carmine (E132).The printing ink for the 10 mg capsule contains shellac, iron oxide black (E172), propylene glycol and ammonium hydroxide. The printing ink for the 25 mg and 50 mg capsule contains shellac, titanium dioxide (E171), propylene glycol, ammonium hydroxide and simeticone.

What Clomipramine looks like and contents of the pack:

Clomipramine 10 mg capsules are red and yellow hard gelatin capsules marked 'G CI10'.
Clomipramine 25 mg capsules are red and orange hard gelatin capsules marked 'G CI25'.
Clomipramine 50 mg capsules are red and blue hard gelatin capsules marked 'G CI50'.

The capsules are available in blisters or plastic containers of 5, 7, 10, 14, 15, 20, 21, 25, 28, 30, 56, 60, 84, 90, 100, 112, 120, 168 and 180 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Viatris,
Station Close, Potters Bar, EN6 1TL, United Kingdom.

Manufacturer:
Mylan Hungary Kft , Mylan utca 1, Komârom,2900, Hungary

Temmler Pharma GmbH, Temmlerstrasse 2, Marburg, Hessen, 35039, Germany.

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VIATRIS

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New Supplier Code	51767785	3D Render ID	N/A
Superseded Supplier Code	51766080	GTIN/PC	N/A

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