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#### Package leaflet: Information for the user

### Clomipramine 10 mg, 25 mg and 50 mg Capsules clomipramine hydrochloride

**Read all of this leaflet carefully before you start taking this medicine.**

- 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. Do not pass it on to others. It may harm them, even if their symptoms 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 Capsules are and what they are used for
2. Before you take Clomipramine Capsules
3. How to take Clomipramine Capsules
4. Possible side effects
5. How to store Clomipramine Capsules
6. Further information

#### 1. What Clomipramine Capsules are and what they are used for

Clomipramine belongs to a group of drugs called tricyclic antidepressants.

Clomipramine is used:

- to treat depression
- to treat phobias and obsessive states
- to treat cataplexy (collapse) associated with narcolepsy (a sleep disorder).

#### 2. Before you take Clomipramine Capsules

##### Do NOT take Clomipramine if you:

- are allergic (hypersensitive) to clomipramine hydrochloride, tricyclic antidepressants or any of the other ingredients of this medicine
- have severe liver problems
- have recently had a heart attack or you suffer from any other heart problems
- have difficulty in passing urine
- have narrow angle glaucoma (loss of vision due to abnormally high pressure in the eye)
- suffer from mania (a mood disorder characterised by high levels of excitement and activity)
- are taking, or have taken within the last three weeks a medicine for depression called a monoamine oxidase inhibitor (MAOI)
- you are aged under 18.

##### Take special care with Clomipramine

Tell your doctor before you start to take this medicine if you:

- suffer from epileptic fits
- have brain damage
- had a brain injury
- have irregular heartbeat or other problems with your heart
- have you been diagnosed as having a low level of potassium in your blood
- have a blood disorder
- have low blood pressure
- are undergoing withdrawal from alcohol or other drugs
- have problems with your thyroid
- have a history of glaucoma (increased pressure in the eye), have narrow angle glaucoma or problems passing urine
- have a tumour of the adrenal gland (phaeochromocytoma or neuroblastoma)
- are having electroconvulsive therapy (ECT)
- suffer from panic disorders or anxiety
- suffer from chronic constipation
- wear contact lenses
- suffer from schizophrenia or other mental disorder
- are pregnant or breast-feeding
- are elderly, as you are more likely to experience side effects such as hallucinations, psychiatric disorders, agitation, confusion, low blood pressure on standing causing dizziness, light-headedness or fainting.

##### 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 (less than 25 years old) 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.

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

Tell your doctor or dentist 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.

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

If you think your symptoms are getting worse, go and see your doctor.

You may get withdrawal symptoms if Clomipramine is stopped abruptly.

#### 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 to 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.

#### Taking other medicines

Do NOT take Clomipramine in combination with, or if you have taken in the last 21 days medicines for depression particularly MAOIs e.g. tranylcypromine, moclobemide phenelzine.

Talk to your doctor if you are taking any of the following:

- medicines for other mental illnesses such as schizophrenia or manic depression e.g. thioridazine, lithium
- medicines for depression - SSRIs e.g. fluoxetine, fluvoxamine; tricyclic and tetracyclic antidepressants e.g. amitriptyline, dothiepin, maprotiline, barbiturates, benzodiazepines
- pimozide (used to treat mental illness)
- anaesthetics (used for the temporary loss of bodily sensation)
- barbiturates e.g. phenobarbital
- antihistamines e.g. cetirizine
- sedatives (drugs used to relieve anxiety) e.g. diazepam
- medicines to treat nasal congestion e.g. phenylephrine, phenylpropanolamine
- sympathomimetic drugs e.g. adrenaline, ephedrine, isoprenaline, noradrenaline, (also found in medicines you can buy without a prescription to relieve a blocked nose)
- anticholinergic drugs (drugs which block some nerve endings and stops glands secreting, speeding up the heart and making some muscles relax) e.g. biperiden, phenothiazine, atropine
- levodopa (used to treat Parkinsonism)
- high blood pressure or irregular heartbeat drugs e.g. disopyramide, procainamide, amiodarone and sotalol, guanethidine, betanidine, reserpine, clonidine, alpha-methyl dopa or quinidine
- betablockers (used to treat heart disease) e.g. atenolol
- diuretics (water tablets) e.g. bendroflumethiazide, furosemide
- disulfiram (used to treat alcoholism)
- cimetidine (to reduce acid indigestion)
- methylphenidate (to treat Attention Deficit Disorder (ADD))
- blood thinning drugs e.g. coumarin or warfarin
- nicotine
- oestrogen (included in birth control pills and hormone replacement therapy (HRT))
- anticonvulsants (used to treat fits) e.g. carbamazepine, phenytoin
- strong painkillers such as morphine or morphine related substances e.g. codeine, dihydrocodeine
- drugs of abuse including Ecstasy
- medicines, called protease inhibitors, used to treat Human Immunodeficiency Virus e.g. ritonavir, indinavir
- medicine called terbinafine used orally to treat skin, hair or nail infections due to fungus
- quinine (used for the treatment of high fever)
- pentamidine (used to treat viral infection)
- terfenadine used to treat symptoms of allergies such as rash, runny nose, watery eyes, hives etc.
- buprenorphine - 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.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

#### Taking Clomipramine with food and drink

Do not take alcohol while taking Clomipramine as it may affect you more than usual.

#### Pregnancy and breast-feeding

If you are pregnant, planning to become pregnant or breast-feeding, ask your doctor for advice before taking this medicine.

If you take Clomipramine during pregnancy your baby may have low or high blood pressure, shaking or spasms, shortness of breath, lethargy, stomach pain and irritability when born.

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).

Ask your doctor or pharmacist for advice before taking any medicine.

#### Driving and using machines

Clomipramine Capsules may cause drowsiness and blurred vision, if affected do not drive or operate machinery.

#### Clomipramine Capsules contain lactose

Patients who are intolerant to lactose should note that Clomipramine Capsules contain a small amount of 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 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 Clomipramine Capsules

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

If you see another doctor or go into hospital, let them or the staff know what medicines you are taking.

Pharma Code

Pharma Code

Pharma Code

Pharma Code

The capsules should be swallowed preferably with a glass of water.

The usual dose is:

#### Depression

- **Adults:** initially, 10 mg a day. Your doctor may increase this to 30-150 mg daily, with a maximum of 250 mg daily, taken as divided doses or as a single dose at bed time.
- **Elderly:** initially 10 mg a day. Your doctor may increase this to 30-75 mg a day.

#### Phobias and obsessive states

- **Adults:** initially 25 mg a day which may be gradually increased if necessary.
- **Elderly:** initially 10 mg a day which may be gradually increased if necessary.

This medicine may take up to 4 weeks to work. You may feel more anxious at the start of treatment but this will normally decrease after two weeks.

#### Cataplexy associated with narcolepsy

- **Adults (including the elderly):** Initially, 10 mg a day which may be gradually increased if necessary, to between 10-75 mg a day.

#### Children and adolescents (0-17 years of age):

Clomipramine is not recommended for use in children and adolescents.

#### If you take more Clomipramine than you should

If you (or someone else) take too many capsules all together, or if you think a child has swallowed any of the capsules, contact your nearest hospital casualty department or your doctor immediately. An overdose is likely to cause drowsiness, stupor, coma, difficulty in controlling movements, agitation, enhanced reflexes, restlessness, fits, muscular rigidity, involuntary jerky movements, shock, low blood pressure, a fast or abnormal heart rate, vomiting, fever, dilated pupils, breathing problems, sweating, blue colour to the skin, passing little or no urine. Please take this leaflet, any remaining capsules and the container with you to the hospital or doctor so that they know which capsules were consumed.

#### If you forget to take Clomipramine

If you forget to take a capsule, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose. Take the remaining doses at the correct time.

#### If you stop taking Clomipramine

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.

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 product, ask your doctor or pharmacist.

## 4. Possible side effects

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

If the following happens, stop taking the capsules and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

If you have any mood changes e.g. increased anxiety, aggression or agitation, you should tell your doctor immediately, as this medicine may not be suitable for you, he may ask you to stop taking it.

The following side effects have been reported at the approximate frequencies shown:

#### Very common (may affect more than 1 in 10 people):

- dry mouth
- visual disturbance e.g. blurred vision
- problems passing urine
- sweating
- constipation
- increased appetite and weight gain
- drowsiness
- restlessness
- tiredness and dizziness
- headaches
- involuntary muscle movements, twitching of the muscles
- uncontrolled shaking
- feeling sick
- sexual problems, difficulty in getting or maintaining an erection.

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

- hot flushes
- pupil dilatation
- changes and disturbances in heart rhythm
- fall in blood pressure on standing up which causes dizziness, light-headedness or fainting
- anxiety, agitation
- mania
- aggressiveness
- confusion with disorientation and hallucinations
- dream and sleep disturbances
- worsening of depressive symptoms
- yawning
- impaired memory and concentration, a sense of being disinterested, elevated mood and hyperactivity, excitement, depersonalisation
- muscle slackness, weakness or spasm, 'pins and needles', tingling and numbness sensation, reduced ability of muscle to stretch
- speech disorder
- being sick
- loss of appetite
- diarrhoea
- abdominal disorders
- breast enlargement and milk production in women even if they are not breast-feeding
- an unpleasant taste
- ringing in the ears

- allergic reactions which may lead to skin rash, sensitivity to light and itching
- palpitation
- ECG changes in patients of normal cardiac status
- abnormal liver function test.

Tell your doctor if you have any of the following:

#### Uncommon (may affect up to 1 in 100 people):

- high blood pressure
- irregular heartbeat
- mood changes including aggression
- movement disorders
- fits.

#### Very Rare (may affect less than 1 in 10,000 people):

- glaucoma (loss of vision due to abnormally high pressure in the eye)
- heart problems
- psychotic symptoms (increased appetite, restlessness, drowsiness, tiredness)
- high body temperature
- inflammation of the liver (including jaundice characterised by yellowing of the skin and whites of the eyes)
- inflammation of lungs
- low blood pressure
- low blood sodium levels (syndrome of inappropriate antidiuretic hormone)
- swelling (oedema)
- hair loss
- blood disorders (characterised by abnormal bruising of the skin or possibly fever or sore throat)
- coloured spots and patches on the skin
- abnormal EEG (test that measures and records the electrical activity of your brain).

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

- abnormal muscle breakdown
- unpleasant feeling of inner restlessness
- suicidal thoughts and behaviour (see Section 2 for more information).
- damage to the heart muscle (cardiomyopathy)
- heart failure

#### Children and Adolescents

Clomipramine should not be used in the treatment of depressive states, phobias or cataplexy associated with narcolepsy for children and adolescents under the age of 18 years as long-term safety effects concerning growth, maturation and cognitive and behavioural development of Clomipramine in this age group have not yet been demonstrated.

Also, patients under 18 may have an increased risk of side effects such as suicidal thoughts, harming themselves and hostility (predominately aggression, oppositional behaviours and anger) when they take drugs like Clomipramine. Despite this, your doctor may prescribe Clomipramine for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed Clomipramine for you (or your child) and you want to discuss this, please go back to your doctor.

You should inform your doctor if any of the symptoms listed above develop or worsen when patients under 18 are taking Clomipramine.

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

**Most of the side effects are 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.**

#### 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](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 Clomipramine Capsules

Keep out of the sight and reach of children.

Do not store above 25°C. Store in the original package. Do not transfer them to another container. Do not use Clomipramine after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month. 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. Further information

#### What Clomipramine Capsules contain:

The active ingredient is clomipramine hydrochloride. The other ingredients are lactose monohydrate, maize starch, povidone (E1201), sodium starch glycolate (E576), sodium laurilsulfate, magnesium stearate (E572), gelatin, yellow iron oxide (E172), red iron oxide (E172), black iron oxide (E172), titanium dioxide (E171). The 25 mg and 50 mg capsules also contain indigotine (E132). The 25 mg capsule also contains erythrosine (E127). The printing ink contains shellac, black iron oxide (E172) and propylene glycol (E1520).

#### What Clomipramine Capsules look like and contents of the pack:

Clomipramine 10 mg Capsules are hard capsules, brown and yellow, printed '1806'. Clomipramine 25 mg Capsules are hard capsules, brown and orange, printed '1807'. Clomipramine 50 mg Capsules are hard capsules, brown and blue, printed '1808'.

The product is available in pack sizes of 28, 30, 56, 60, 100, 250, 500 or 1000 capsules.

Not all pack sizes may be marketed.

#### Marketing Authorisation Holder

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