

## Package Leaflet: Information for the user

### Clonactil 25mg Film-coated Tablets Clonactil 50mg Film-coated Tablets Clonactil 100mg Film-coated Tablets

#### Chlorpromazine 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 further questions, please 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

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

#### 1. What Clonactil is and what it is used for

Clonactil tablets contain the active substance chlorpromazine. Chlorpromazine belongs to a group of drugs known as antipsychotics, which act on the central nervous system.

#### Clonactil Tablets are used for:

- The treatment of behavioural disturbances, including schizophrenia, mania and hypomania
- The short-term treatment of anxiety, agitation and violent or impulsive behaviour
- The treatment of persistent hiccup and nausea and vomiting associated with terminal illness.

#### 2. What you need to know before you take Clonactil Tablets

##### Do Not take Clonactil Tablets

- if you are allergic to chlorpromazine or any of the other ingredients of this medicine (listed in section 6)
- if you have a low blood cell count (bone marrow depression)
- if you have prostate trouble
- if you have glaucoma (painful eyes with blurred vision)
- if you are breast-feeding
- if you are in or have ever previously been in a comatose state while taking barbiturates (medicines to treat fits, e.g., phenobarbital), opiates (medicines to treat pain, e.g., tramadol) or drinking alcohol
- if you are taking medicinal products that may affect your blood. Talk to your doctor, he/she will know what these medicinal products are.
- if you are taking a dopaminergic antiparkinsonism drug
- if you are breast-feeding
- if you are taking citalopram or escitalopram
- if you have a history of low white blood cell count
- if you have urine retention due to a prostate disorder.

## Warnings and precautions

Talk to your doctor or pharmacist before taking Clonactil Tablets

- if you are allergic to other phenothiazine medicines such as prochlorperazine
- if you suffer from liver or kidney problems
- if you suffer from epilepsy (fits) or have had fits in the past
- if you have had, or any member of your family has had, any disease that has affected the heart or if you blood circulation
- if you have ever had a stroke or are at risk of having a stroke. You are at greater risk of stroke if you are elderly and are being treated for dementia, if you smoke, have high cholesterol, diabetes, high blood pressure, irregular heartbeat or if you are obese.
- if you have depression
- if you have ever had a low number of white blood cells (agranulocytosis). This means you may get infections more easily than usual
- if you are taking any medicines used to calm emotional and mental conditions
- if you or someone else in your family has a history of blood clots, as medicines like this have been associated with formation of blood clots
- if you have an underactive thyroid gland (hypothyroidism)
- if you have Parkinson's disease
- if you have a tumour of your adrenal gland
- if you suffer from the condition myasthenia gravis (muscular weakness)
- if you have prostate trouble
- if you have had glaucoma (painful eyes with blurred vision)
- if you suffer from any metabolic disorder such as low levels of calcium, magnesium or potassium in the blood
- if you suffer from dehydration or have recently lost a lot of blood
- if you have an infection or fever, a reduction in blood cells which can make the skin pale and cause weakness or breathlessness, or bleeding. Your doctor may carry out blood tests.
- if you are elderly. You may be at risk of side effects such as uncontrollable movements of the mouth, tongue and limbs (tardive dyskinesia)
- if you are not eating properly
- if you have heart problems or a family history of heart problems, such as an irregular heartbeat
- if you have ever had alcohol problems

If you are to undergo **surgery** you should inform the surgeon and anaesthetist of your treatment with chlorpromazine as the combined use of both anaesthetic and chlorpromazine may decrease your blood pressure (low blood pressure).

As the medicine may make your skin more sensitive to the effects of the sun, you should **avoid exposure to direct sunlight** during treatment.

Avoid contact with the skin if the tablets are broken or crushed.

If you are **elderly** you may be more sensitive to the effects of Clonactil Tablets, particularly if you have had a stroke in the past, and during very hot or very cold weather, as there is a risk of **hyperthermia** (high body temperature) or **hypothermia** (low body temperature).

As chlorpromazine can occasionally affect the heart, your doctor will arrange regular monitoring of your heart rhythm. As some of these effects can be made worse by lack of certain elements known as electrolytes in your blood, your doctor will also monitor these on a regular basis.

Your doctor may need to carry out regular blood tests during treatment with chlorpromazine.

### **Other medicines and Clonactil tablets**

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

**Please consult your doctor if you are taking:**

- The following medicines to treat high blood pressure:
  - Alpha-blocking medicines such as doxazosin
  - Anti-hypertensives such as guanethidine and clonidine
  - Beta-blocking medicines such as atenolol, propranolol and bisoprolol
  - ACE inhibitors such as enalapril, lisinopril and perindopril
  - Disopyramide, amiodarone, quinidine, procainamide or sotalol (medicines to control your heartbeat)
  - Calcium channel blockers such as nifedipine, diltiazem and verapamil
  - Angiotensin II antagonists such as losartan and valsartan
- Other medicines used to calm emotional and mental problems such as olanzapine and prochlorperazine
- Some medicines used for cancer (cytotoxics), such as busulfan and doxorubicin
- Anticholinergic drugs, which affect the nervous system (e.g. atropine and hyoscine)
- Amphetamine (used to treat narcolepsy and attention deficit hyperactivity disorder)
- Adrenaline (used to treat cardiac arrest)
- Antacids (used to neutralise excess stomach acid)
- Medicines which can alter electrolytes (salt levels) in your blood such as diuretics including furosemide
- Medicines used to treat Parkinson's disease (e.g. levodopa, carbidopa)
- Barbiturates (sleeping drugs) and other sedatives
- Medicines used for depression such as amitriptyline, imipramine and fluoxetine
- Drugs used to treat diabetes (hypoglycaemic agents) such as chlorpropamide, glibenclamide, tolbutamide or insulin
- Desferrioxamine (used to treat iron poisoning)
- Other medicines used to treat behavioural disturbances (e.g. thioridazine)
- Cimetidine (used to treat stomach ulcers)
- Metoclopramide (used to treat stomach upset)
- Tetrabenazine (used to treat movement disorders)
- Ritonavir (used to treat HIV)
- Medicines used to treat pain (e.g. morphine and codeine) and anaesthetics
- Medicines used to treat epilepsy (e.g. phenobarbital, phenytoin and carbamazepine)
- Antibiotics (used to treat infections) such as moxifloxacin and erythromycin
- Haloperidol, lithium and sertindole (medicines used to treat mental disturbances)
- Medicines used to treat depression called monoamine oxidase inhibitors (MAOI), such as moclobemide and selegiline

**Clonactil Tablets with food and drink**

You should avoid alcohol while taking this medicine as it may increase the sedative effects of chlorpromazine.

**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. Chlorpromazine should only be used during pregnancy if considered essential by your doctor.

The following symptoms may occur in newborn babies, of mothers that have used Clonactil in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Do not take Clonactil Tablets while breast-feeding. Chlorpromazine is passed to your baby through your breast milk. If you have to continue treatment with Clonactil Tablets, you should stop breast-feeding.

Chlorpromazine may make it difficult for a woman to get pregnant due to it reducing her fertility.

**Driving and using machines:**

This medicine may cause some people, especially elderly patients, to become drowsy, dizzy, light-headed, clumsy, unsteady or less alert than normal. If you are affected, do not drive or operate dangerous machinery.

**Clonactil Tablets contain 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.

**3. How to take Clonactil Tablets**

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. Your doctor will start you on a low dose to begin with. The dose will be gradually increased and your doctor will monitor you closely until a suitable dose is reached.

**Adults**

- Behavioural disturbances/anxiety: This is usually 75 – 300 mg daily, but some patients need up to 1000 mg (1g) daily.
- Nausea and vomiting: The recommended dose is 10 – 25 mg every 4 to 6 hours.
- Treatment of hiccup: The recommended initial dose is 10 – 25 mg every 6 to 8 hours if necessary. This may be increased to 25 – 50 mg every 6 to 8 hours by your doctor.

**Elderly people**

- Behavioural disturbances/anxiety: The recommended dose is 10 – 25 mg once or twice daily. The recommended starting dose is one third to one half the adult dose, with a more gradual increase in dosage.
- Nausea and vomiting: The recommended starting dose is one third to one half the adult dose. If required your doctor may increase the dose.

**Use in children**

- Behavioural disturbances/anxiety:
  - 1 – 5 years: 0.5 mg per kg of body weight every 4 to 6 hours. Do not exceed 40 mg daily.
  - 6 – 12 years: One third to one half the adult dose. Do not exceed 75 mg daily.
- Nausea and vomiting:
  - 1 – 5 years: 0.5 mg per kg of body weight every 4 to 6 hours. Do not exceed 40 mg daily.
  - 6 – 12 years: 0.5 mg per kg of body weight every 4 to 6 hours. Do not exceed 75 mg daily.

If this medicine is prescribed for a child make sure that the tablets are taken as stated on the pharmacist's label.

Swallow the tablets with a drink of water.

DO NOT CRUSH OR CHEW THE TABLETS.

**If you take more Clonactil Tablets than you should**

Contact your doctor or pharmacist or telephone your nearest casualty department immediately.

Remember to take the pack and any remaining tablets with you.

The symptoms of overdose may include drowsiness or loss of consciousness, low blood pressure, irregular heartbeat, hypothermia (low body temperature) or involuntary movement.

**If you forget to take Clonactil Tablets**

If you forget to take a dose, take it as soon as you remember. If your next dose is due within 2 hours, do not take the missed dose. Just take the next dose at the usual time.

**If you stop using Clonactil Tablets**

Do not stop or change your treatment before talking to your doctor. Withdrawal symptoms can occur after you stop treatment, so gradual withdrawal is advisable. Withdrawal symptoms include feeling sick (nausea), being sick (vomiting), sweating, and difficulty sleeping (insomnia). Your illness may also come back and you may have movements that you cannot control, mainly of the tongue, mouth, jaw, arms and legs.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

<b>4. Possible side effects</b>
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Like all medicines, this medicine can cause side effects, although not everyone gets them.

If you experience any of the following **STOP** taking this medicine and contact your doctor **IMMEDIATELY**:

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

- you have movements that you cannot control, mainly of the tongue, mouth, jaw, arms and legs
- trembling, muscle stiffness or spasm, slow movement, producing more saliva than usual or feeling restless

Common (may affect up to 1 in 10 people)

- you have a fit (seizure)
- alteration of the heart rhythm (called ‘prolongation of the QT interval’, seen on ECG, electrical activity of the heart).

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

- you have an allergic reaction. The signs may include: rash, itching, fever, difficulty in breathing or wheezing, chills, swollen eyelids, lips, tongue or throat
- you have a very fast, uneven or forceful heartbeat (palpitations). You may also have breathing problems such as wheezing, shortness of breath, tightness in the chest and chest pain. These could be signs of very serious life threatening heart problems
- you have joint aches and pains, swollen joints, feel tired or weak with chest pain and shortness of breath. These could be signs of an illness called ‘systemic lupus erythematosus’ (SLE)
- you have yellowing of the skin or eyes (jaundice) and your urine becomes darker in colour. These could be signs of liver damage
- you have frequent infections such as fever, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called ‘leucopenia’
- you have a high temperature, sweating or stiff muscles, fast heartbeat, fast breathing and feel confused, drowsy or agitated. These could be signs of a serious but rare side effect called ‘neuroleptic malignant syndrome’

- you get a bloated feeling and cramping pain in the abdomen (stomach) be sick (vomit), have indigestion, heartburn, upset stomach, constipation, loss of appetite, dry mouth. This could be caused by an obstruction or blockage of the intestine
- you have pain in your abdomen with vomiting and diarrhoea
- you have a long lasting painful erection of the penis
- you bruise more easily than usual. This could be because of a blood disorder called ‘thrombocytopenia’
- you have blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately.

If you experience any of the following side effects **tell your doctor:**

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

- feeling dizzy, lightheaded or faint when you stand or sit up quickly (due to low blood pressure).

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

- you are breathing more slowly or less deeply than normal
- changes in skin or eye colour after having Chlorpromazine for a long time
- problems with eyesight
- rigid or stiff muscles, trembling or shaking, difficulty moving
- passing large amounts of urine, excessive thirst and having a dry mouth or skin. You may be more likely get infections such as thrush. This could be due to too much sugar in your blood (hyperglycaemia)
- unusual eye movements (including rolling of the eyes)
- your neck becomes twisted to one side
- your jaw is tight and stiff
- you have difficulty in passing water (urine)
- feeling tired, weak, confused and have muscles that ache, are stiff or do not work well. This may be due to low sodium levels in your blood.

**Tell your doctor or pharmacist if any of the following side effects gets serious or lasts longer than a few days:**

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

- dry mouth
- feeling drowsy or sleepy
- putting on weight.

Common (may affect up to 1 in 10 people)

- abnormal production of breast milk in men and women
- loss of menstrual periods
- feeling anxious.

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

- breast enlargement in men
- difficulty in getting or keeping an erection (impotence)
- reduced sexual desire in women
- difficulty sleeping (insomnia)
- feeling agitated
- being more sensitive to the sun than usual

- stuffy nose
- skin rashes
- tiredness, low mood.

In elderly people with dementia, a small increase in the number of deaths has been reported for patients taking antipsychotics compared with those not receiving antipsychotics.

**Withdrawal effects:** If this medicine is stopped suddenly nausea, vomiting and difficulty sleeping (insomnia), tremor (shaking), jerky body movements and the inability to control movements of the hands and body can occur.

If any of the side effects get serious, or if you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

#### 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 HPRA

Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Clonactil Tablets**

Keep this medicine out of sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep the container tightly closed. Store in the original container in order to protect from light.

Do not throw away 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 Clonactil tablets contain:**

The active substance is chlorpromazine hydrochloride. The other ingredients are:

*Tablet core:*

- Lactose monohydrate
- Povidone
- Magnesium stearate
- Maize starch

*Film-coat:*

- Hypromellose
- Macrogol
- Titanium dioxide (E171)

Each film-coated tablet contains 25 mg, 50 mg or 100 mg chlorpromazine hydrochloride.

#### **What Clonactil tablets look like and contents of the pack:**

Clonactil 25 mg, 50 mg and 100 mg tablets are white, circular, biconvex, film-coated, tablets engraved with CZ1, CZ2 or CZ3 respectively on one side.

Clonactil tablets are available in packs containing 25, 50, 100, 250, 500 or 1,000 tablets.

Not all pack sizes may be marketed.

**Marketing authorisation holder and manufacturer:**

Clonmel Healthcare Ltd  
Waterford Road  
Clonmel, Co. Tipperary  
Ireland

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