

PACKAGE LEAFLET: INFORMATION FOR THE USER

Chlorpromazine 25mg, 50mg, 100mg Tablets

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

1. What Chlorpromazine Tablets are and what they are used for

Chlorpromazine tablets belong to a group of drugs known as phenothiazines, which act on the central nervous system. They are used to treat the following conditions: **schizophrenia** and **other psychoses** particularly **paranoia** (delusions and feelings of persecution), **mania** (overactive behaviour and **hypomania** (elated moods and excitability), **anxiety**, **agitation** and **violent or dangerously impulsive** behaviour.

Chlorpromazine is also used for prolonged periods of **hiccups**, **feeling or being sick** (when other drugs have failed), to **lower body temperature** and for **childhood schizophrenia** and **autism** (learning and communication difficulties).

2. What you need to know before you take Chlorpromazine Tablets

Do not take Chlorpromazine Tablets and tell your doctor if you:

- are **allergic** (hypersensitive) to Chlorpromazine, other phenothiazines or to any of the other ingredients in the tablets (see Section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- have a low number of blood cells (bone marrow depression)
- have an increased pressure in the eye (glaucoma)
- are taking a dopaminergic antiparkinsonism drug
- are breast-feeding
- are taking citalopram or escitalopram
- have a history of low white blood cell count
- have urine retention due to a prostate disorder.

Warnings and precautions

Talk to your doctor or pharmacist before taking Chlorpromazine Tablets if you:

- or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots
- have **liver or kidney** disease
- have **epilepsy** or have had **fits** (seizures)
- have **Parkinson's** disease
- have **hypothyroidism** (reduced activity of the thyroid gland)
- have **heart disease** such as heart failure
- have ever had a **stroke**
- have **myasthenia gravis** (a condition where muscles become easily tired and weak leading to difficulty breathing)
- have low levels of potassium, calcium and magnesium. Your doctor may do blood tests to check on these
- have **phaeochromocytoma** (high blood pressure due to a tumour near the kidney)
- have **glaucoma** (raised eyeball pressure)
- have **diabetes and are taking drugs** to reduce blood sugar (as Chlorpromazine Tablets may reduce their effect)
- have enlargement of the **prostate**.
- have **depression**
- have ever had **alcohol problems**
- have a low number of white blood cells (agranulocytosis). This means you may get infections more easily than normal you are elderly (65 years of age or older).

Other medicines and Chlorpromazine Tablets

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

- medicines for indigestion and heartburn (antacids)
- medicines for diabetes
- medicines for high blood pressure or prostate problems such as doxazosin and terazosin
- medicines for Parkinson's disease such as levodopa
- medicines for fits (epilepsy) such as carbamazepine or phenobarbital
- medicines to control your heartbeat such as amiodarone, disopyramide or quinidine
- medicines to help you sleep (sedatives)
- medicines for depression or amphetamines
- other medicines used to calm emotional and mental problems such as olanzapine or prochlorperazine
- some medicines used for high blood pressure such as guanethidine, clonidine or propranolol
- some medicines used for infections (antibiotics) such as moxifloxacin
- some medicines used for cancer (cytotoxics)
- medicines which can alter electrolytes (salt levels) in your blood
- amphetamines – used for Attention Deficit Hyperactivity Disorder (ADHD)
- anticholinergic medicines – includes some medicines used for irritable bowel syndrome, asthma or incontinence
- adrenaline – used for life threatening allergic reactions
- deferoxamine – used when you have too much iron in your blood
- lithium – used for some types of mental illness.

Chlorpromazine Tablets with alcohol

Alcohol must not be used with Chlorpromazine. This is because alcohol can increase the effects of Chlorpromazine and cause serious breathing problems.

Pregnancy and breast-feeding

Talk to your doctor or pharmacist before having this medicine if you are pregnant, might become pregnant or think you may be pregnant. The following symptoms may occur in newborn babies of mothers that have used Chlorpromazine 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 breast-feed if you are being given Chlorpromazine. This is because small amounts may pass into the mother's milk. If you are breast-feeding or planning to breast-feed talk to your doctor or pharmacist before taking this medicine.

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.

Chlorpromazine Tablets contain lactose

If a doctor has told you that you have an intolerance to some sugars, check with your doctor before taking these tablets, as they contain a type of sugar called lactose.

3. How to take Chlorpromazine Tablets

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

You will be prescribed the lowest dose needed to control your symptoms. **Do not stop taking your medicine or change the dose** unless your doctor tells you to.

The tablets should be swallowed with a glass of water.

Dose for schizophrenia, other psychoses, anxiety and agitation

Adults: Start with 25mg three times a day or 75mg at bedtime.

This may be increased by 25mg a day to an effective dose. This is usually 75mg - 300mg daily, but some patients need up to 1000mg (1g) daily.

Elderly weak or infirm patients: Start with $\frac{1}{3}$ - $\frac{1}{2}$ usual adult dose with a more gradual increase in dose.

Children 6-12 years: $\frac{1}{3}$ - $\frac{1}{2}$ adult dose to a maximum daily dose of 75mg.

Children 1-5 years: 0.5mg per kg body weight every 4-6 hours to a maximum daily dose of 40mg.

Children under 1 year: Not to be used unless the need is life saving.

Dose for nausea and vomiting

Adults: 10mg-25mg every 4-6 hours.

Elderly weak or infirm patients: Start with $\frac{1}{3}$ - $\frac{1}{2}$ adult dose. Your doctor will then increase the dose as needed.

Children 6-12 years: 0.5mg per kg bodyweight every 4-6 hours. Maximum daily dose 75mg.

Children 1-5 years: 0.5mg per kg bodyweight every 4-6 hours. Maximum daily dose 40mg.

Children under 1 year: Not to be used unless the need is life saving.

Dose for hiccups

Adults, elderly, weak or infirm patients: 25-50mg 3-4 times a day.

Children: Not recommended in children.

If you don't feel better

If you don't feel the tablets are working as well after you have taken them for a short time (3-4 days), **do not increase** the dose; instead check with your doctor.

If you take more Chlorpromazine Tablets than you should

If you accidentally take more tablets or somebody else takes any tablets, contact a doctor or go to your nearest hospital casualty department at once. Take any remaining tablets with you and the container or packaging, so they can be identified.

If you forget to take Chlorpromazine Tablets

If you miss a dose, skip the missed dose and go back to your regular schedule. **Do not take a double dose** to make up for a forgotten dose.

If you stop taking Chlorpromazine tablets

Withdrawal symptoms can occur after you stop treatment (see Section 4), so gradual withdrawal is advisable. **Do not stop taking** the tablets **without talking to your doctor or pharmacist**.

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. Do not be alarmed by this list of side effects. Most people take Chlorpromazine without any problems

Tell your doctor or pharmacist or go to a hospital straight away if:

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.

Tell your doctor or pharmacist as soon as possible if you have any of the following side effects:

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 the Yellow Card Scheme at: 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 Chlorpromazine Tablets

Do not store above 25°C. Store in a dry place, **protect from light**. Keep the container tightly closed. 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 carton and blister after EXP. The expiry date refers to the last day of that month. 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 Chlorpromazine Tablets contain

The active ingredient (which makes the tablets work) is chlorpromazine hydrochloride. The tablets also contain lactose, maize starch, povidone, sodium starch glycolate, colloidal anhydrous silica, magnesium stearate, hypromellose, purified water, ethylcellulose, diethylphthalate and titanium dioxide (E171).

What Chlorpromazine Tablets look like and contents of the pack

The tablets are round, white, and film coated. The 25mg tablets are marked with CPZ25. The 50mg tablets are marked with CPZ50. The 100mg tablets are marked with CPZ100. Available pack sizes are 28, 30, 50, 56, 60, 84, 100, 250, 500 and 1,000 tablets. Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer

Dr. Reddy's Laboratories (UK) Ltd., 6 Riverview Road, Beverley, HU17 0LD, UK.

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