

Package leaflet: Information for the user

Chlorpromazine 25 mg Tablets

Chlorpromazine 50 mg Tablets

Chlorpromazine 100 mg Tablets

Chlorpromazine

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 is and what it is 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 to Chlorpromazine, other phenothiazines (such as prochlorperazine or trifluoperazine) or to any of the other ingredients in the tablets (listed in 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 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.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Chlorpromazine Tablets.

Warnings and precautions

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

- have liver or kidney disease
- have hypothyroidism (reduced activity of the thyroid gland)
- have heart disease such as heart failure or a family history of heart problems
- have ever had a stroke
- have Parkinson's disease
- have epilepsy or have had fits (seizures)
- have depression
- have ever had alcohol problems
- have enlargement of the prostate
- have had glaucoma (Painful eyes with blurred vision)
- have a tumour on the adrenal gland called 'phaeochromocytoma' (high blood pressure due to a tumour near the kidney)
- have myasthenia gravis (a condition where muscles become easily tired and weak leading to difficulty breathing)
- have a low number of white blood cells (agranulocytosis). This means you may get infections more easily than normal
- have low blood levels of potassium, calcium and magnesium. Your doctor may do blood tests to check on these.
- or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots
- notice yellowing of the skin or eyes (jaundice) and urine becomes darker in colour, or you are not eating properly. These could be signs of liver damage.
- are allergic to other phenothiazine medicines such as prochlorperazine or you suspect any allergic reaction while taking chlorpromazine
- are elderly (65 years of age or older)
- are elderly, particularly during very hot or very cold weather in these conditions, you could be at risk of hyperthermia or hypothermia
- have low blood pressure or feel dizzy when you stand up.
- have diabetes or have high levels of sugar in your blood (hyperglycaemia) and are taking drugs to reduce blood sugar (as Chlorpromazine Tablets may reduce their effect). Your doctor may want to monitor you more closely.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before being given Chlorpromazine Tablets.

Skin reaction

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS), have been reported with the use of Chlorpromazine Tablets. DRESS appears initially as flu-like symptoms and a rash on the face, than an extended rash with a high body temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes. If you develop a serious rash or another of these skin symptoms, stop taking Chlorpromazine and contact your doctor or seek medical attention immediately.

Exposure to sunlight

Chlorpromazine tablets can make your skin more sensitive to sunlight. Keep out of direct sunlight while taking this medicine.

Tests

Before and during treatment your doctor may want to carry out some tests. These might include blood tests and an ECG to check your heart is working properly and eye tests. Your doctor may want to carry out tests every year during your child's treatment to evaluate your child's learning capabilities.

Other medicines and Chlorpromazine Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines bought without a prescription, including herbal medicines. This is because Chlorpromazine Tablets can affect the way some other medicines work. Also some medicines can affect the way Chlorpromazine Tablets work.

In particular, tell your doctor or pharmacist if you are taking any of the following:

- 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
- 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
- medicines that may interact in the metabolism of chlorpromazine, examples include ciprofloxacin, oral contraceptives.

Chlorpromazine tablets with alcohol

You must not drink alcohol whilst taking this medicine. This is because this medicine may make you feel drowsy and drinking alcohol will make you feel even more drowsy. Drinking alcohol may also cause serious breathing problems.

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. You should not use this medicine if you are pregnant or breast-feeding unless your doctor feels it is absolutely necessary. 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

Do not drive or use tools or machines if this medicine makes you feel drowsy or if it has affected your eyesight.

Chlorpromazine tablets contains Lactose

This medicine contains **lactose** (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, check with your doctor before taking these tablets.

Sodium content

This medicine contains less than 1 mmol sodium (23 mg) per 25 mg, 50 mg and 100 mg tablet, that is to say essentially 'sodium-free'.

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.

The recommended doses are:

Adults

The recommended dose for adults is 40 mg to 300 mg daily in divided doses

The dose prescribed and how often you should take the doses will depend upon the condition being treated and on your response. You will start treatment on a low dose which will be increased as necessary by your doctor.

Elderly, weak or feeble patients will need to take one third or half the recommended adult dose. Your doctor will gradually increase this dose.

Children

- Children under 1 year should not take this medicine
- Children aged 1 to 5 years: the maximum dose should be no more than 40 mg a day. You must split this dose over the day
- Children aged 6 to 12 years: the maximum dose should be no more than 75 mg a day. You must split this dose over the day.

Your doctor will work out the dose for your child according to their age and weight.

If you take more Chlorpromazine tablets than you should

Talk to a doctor or go to a hospital straight away. Take the medicine pack with you so the doctor knows what you have taken. Signs of an overdose may include drowsiness, low body temperature, low blood pressure, twisting of your limbs, stiffness, shaking, unusual heart beats and coma.

If you forget to take Chlorpromazine tablets

Do not take a double dose (two doses at the same time) to make up for a forgotten dose. Skip the missed dose then go on as before.

If you stop taking Chlorpromazine tablets

Keep taking Chlorpromazine until your doctor tells you to stop. If you stop taking Chlorpromazine Tablets your illness may come back, and you may have other effects such as feeling or being sick and difficulty sleeping. Your doctor will gradually stop your medicines to prevent these effects happening.

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.

Tell your doctor or pharmacist or go to a hospital straight away if you have any of the following serious side effects:

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 a test called 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 bruise more easily than usual. This could be because of a blood disorder called 'thrombocytopenia'
- you have an increased number of eosinophils (a type of white blood cells)
- You have a decrease in platelet count (cells in the blood that help with clotting)
- 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 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 last 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.

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_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 Chlorpromazine tablets

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

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 glycollate, 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

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Chlorpromazine 25 mg Tablets PL08553/0074

Chlorpromazine 50 mg Tablets PL08553/0075

Chlorpromazine 100 mg Tablets PL08553/0076

Leaflet revised 11/2023