

Chlorpromazine 25 mg Tablets

Chlorpromazine 50 mg Tablets

Chlorpromazine 100 mg Tablets

Active substance: 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 any further questions, ask your doctor, nurse 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, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1. What Chlorpromazine is and what it is used for**
- 2. What you need to know before you take Chlorpromazine tablets**
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1. What Chlorpromazine is and what it is used for

The name of your medicine is Chlorpromazine. It contains the active ingredient chlorpromazine hydrochloride. This belongs to a group of medicines called 'phenothiazines'. It works by blocking the effect of a chemical in the brain.

Chlorpromazine 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 Chlorpromazine tablets

DO NOT TAKE Chlorpromazine tablets if:

You are allergic to Chlorpromazine or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

- You have a low number of blood cells (bone marrow depression).
- You have increased pressure in the eye (glaucoma).
- You are taking a dopaminergic antiparkinsonism drug.
- You are breast-feeding.
- You are taking citalopram or escitalopram.
- You have a history of a low white blood cell count.
- You 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:

- Suffer from liver or kidney problems
- Suffer from epilepsy or have had fits (seizures)
- Have had, or any member of your family has had, any disease that has affected the heart or blood circulation.
- Or someone else in your family has a history of blood clots, as medicines like this have been associated with formation of blood clots.
- Have an underactive thyroid gland (hypothyroidism)
- Suffer from a physical disorder of the brain that causes decreased mental function, such as Parkinson's disease
- Have heart problems or a family history of heart problems
- Have ever had a stroke
- Have a tumour of your adrenal gland called 'phaeochromocytoma'
- Suffer from the condition called 'myasthenia gravis' (muscular weakness)
- Have prostate trouble
- Have had glaucoma (painful eyes with blurred vision)
- Suffer from any metabolic disorder such as low levels of calcium, magnesium or potassium in the blood. Your doctor may do blood tests to check on these.
- Suffer from dehydration or have recently lost a lot of blood
- Are diabetic or have high levels of sugar in your blood (hyperglycaemia). Your doctor may want to monitor you more closely
- 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 usual
- Are elderly (65 years of age or older)
- You are allergic to other phenothiazine medicines such as prochlorperazine or you suspect any allergic reaction while taking Chlorpromazine Tablets.
- Have low blood pressure or feel dizzy when you stand up
- 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
- You are elderly, particularly during very hot or very cold weather. In these conditions, you could be at risk of hyperthermia or hypothermia if you are not sure if any of the above apply to you, talk to your doctor or pharmacist before you take Chlorpromazine Tablets.
- 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).

Skin reactions

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 then 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

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

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 capacity.

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 you buy 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 food, drink and alcohol:

Do not drink alcohol whilst taking this medicine. This is because alcohol can increase the effect of Chlorpromazine and cause serious breathing problems.

Pregnancy, breast-feeding and fertility:

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 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 Tablets. This is because small amounts may pass into mothers' milk. If you are breast-feeding or planning to breast-feed talk to your doctor or nurse before taking this medicine. Ask your doctor or nurse for advice before taking any medicine if you are pregnant or breast-feeding. Chlorpromazine may make it more difficult for a woman to get pregnant due to it reducing her fertility.

Driving and using machines:

You may feel sleepy after having this medicine. If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of Chlorpromazine tablets:

This medicine contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1mmol sodium (23 mg) per tablet, that is to say essentially "sodium free".

3. How to take Chlorpromazine tablets

Always take Chlorpromazine tablets exactly as your doctor has told you. You should 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:

Usually 25 mg three times daily or 75 mg at bedtime to start with. This may be increased by 25 mg a day to an effective dose. This is usually 75 - 300 mg daily, but some patients need up to 1000 mg (1g) daily.

Nausea and vomiting:

The usual dose is 10 - 25 mg every 4 to 6 hours.

Treatment of hiccup:

The usual dose is 25 - 50 mg every 6 to 8 hours.

Elderly or debilitated:

Behavioural disturbances / anxiety:

The usual starting dose is one third to one half the adult dose, with a more gradual increase in dosage.

Nausea and vomiting:

The usual starting dose is one third to one half the adult dose. If required your doctor may increase the dose.

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 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:

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 Chlorpromazine 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 moments that you cannot control, mainly of the tongue, mouth, jaw, arms and legs.

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

4. Possible side effects

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

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

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 QT interval', seen on a test called an ECG).

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, 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

- You have a long lasting, painful erection of

- You have 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
- You have an increased number of eosinophils (a type of white blood cell)
- You have a decrease in platelet count (cells in the blood that help with clotting).

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 Tablets 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 get 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.

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

Store below 25°C.

Store in the original tablet container.

Keep out of reach and sight of children.

Do not use Chlorpromazine tablets after the expiry date stated on the label. 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 dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Chlorpromazine tablets contains

The active substance is Chlorpromazine hydrochloride. The tablets also contain, lactose monohydrate, povidone, magnesium stearate, maize starch, talc, hypromellose, titanium dioxide (E171) and polyethylene glycol.

Each coated tablet contains 25 mg, 50 mg or 100 mg Chlorpromazine.

What Chlorpromazine tablets look like and contents of the pack:

Chlorpromazine 25 mg, 50 mg and 100 mg tablets are white, circular, biconvex, film-coated tablet engraved with "CZ1", "CZ2" or "CZ3", respectively.

Chlorpromazine tablets are available in

packs containing 25, 28, 50, 56, 100, 250, 500 or 1,000 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Northumbria Pharma Limited,

Netpark,

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Stockton-on-Tees,

TS21 3FD,

United Kingdom.

Manufacturer

Custom Pharmaceuticals Limited

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