

Package leaflet: Information for the user
CHLORPROMAZINE 25 mg / 5 ml SOLUTION
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.
- 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. 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
3. How to take Chlorpromazine
4. Possible side effects
5. How to store Chlorpromazine
6. Contents of the pack and other information

1. WHAT CHLORPROMAZINE IS AND WHAT IT IS USED FOR

Chlorpromazine 25 mg / 5 ml Solution belongs to a group of medicines called phenothiazine neuroleptics. It works by blocking the effect of a chemical in the brain.

Chlorpromazine can be used for:

- Schizophrenia in adults and children
- Short term treatment of anxiety
- Hiccups
- Feeling or being sick (where other anti-sickness medicines have not worked)
- Autism

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CHLORPROMAZINE

Do not take Chlorpromazine

- if you are allergic to chlorpromazine or any of the other ingredients in the product (*listed in Section 6*).
- if you have a low number of blood cells (bone marrow depression)
- if you have increased pressure in the eye (glaucoma)
- 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 a low white blood cell count
- if you have urine retention due to a prostate disorder.

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

Warnings and precautions

Talk to your doctor before taking Chlorpromazine:

- if you have liver or kidney problems
- if you have thyroid problems
- if you have heart problems or a family history of heart problems
- if you have ever had a stroke
- if you have Parkinson's disease or dementia
- if you have epilepsy or have had fits (seizures)
- if you have depression
- if you have ever had alcohol problems
- if you have an enlarged prostate gland
- if you have had glaucoma (painful eyes with blurred vision)
- if you have a tumour on the adrenal gland called 'pheochromocytoma'
- if you have a form of muscle weakness called 'myasthenia gravis'
- if you have a low number of white blood cells (agranulocytosis). This means you may get infections more easily than usual
- if you have low blood levels of potassium, calcium and magnesium. Your doctor may do blood tests to check on these
- 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
- if you are not eating properly
- if you are allergic to other phenothiazine medicines such as prochlorperazine
- if you are elderly (65 years of age or older)
- if you are elderly, and the weather is very hot or very cold. In these conditions, you could be at risk of hyperthermia or hypothermia
- if you have low blood pressure or feel dizzy when you stand up
- if you are diabetic or have high levels of sugar in your blood (hyperglycaemia). 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 taking Chlorpromazine.

Other medicines and Chlorpromazine

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

In particular, check with your doctor 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.

Warning: Avoid direct contact with the skin as it may cause dermatitis. If in contact, wash the area thoroughly.

Chlorpromazine with alcohol

Do not drink alcohol whilst being treated with Chlorpromazine. This is because alcohol can increase the effects 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 for advice before taking this medicine.

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 mothers' milk. If you are breast-feeding or planning to breast-feed talk to your doctor before taking this medicine.

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.

Chlorpromazine contains ethanol, sorbitol, aspartame and colour sunset yellow

- **Ethanol:** Each 5 ml dose contains 0.02 g of ethanol, equivalent to 0.48 ml beer, 0.2 ml wine. Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high risk groups such as patients with liver disease, or epilepsy.
- **Sorbitol (E420):** If you have an intolerance to some sugars, contact your doctor before taking this product.
- **Aspartame (E951):** Contains a source of phenylalanine. May be harmful for people with phenylketonuria.
- **Colour Sunset Yellow (E110):** May cause an allergic reaction, and this is more common in people who are also allergic to aspirin.

3. HOW TO TAKE CHLORPROMAZINE

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

Your doctor will advise you, as the dosage is likely to be increased from the initial dose. You should check with your doctor if you are not sure about the dose you should take.

This medicine should only be taken by mouth. Shake well before use.

The recommended doses are:

Adults	Children under 1 year	Children 1-5 years	Children 6-12 years	Elderly or debilitated patients
For schizophrenia, other psychoses, anxiety, childhood schizophrenia and autism:				
Initially, 25 mg three times a day or 75 mg at bedtime, increasing to a dose effective for you, (usually 75 mg to 300 mg, but could be up to 1 g daily).	Do not use unless the need is life-saving.	0.5 mg per kg bodyweight every 4 to 6 hours to a maximum of 40 mg daily.	Initially one-third to half the adult dose to a maximum of 75 mg daily.	Initially one-third to one half the adult dose with a gradual increase in the dose.
Hiccup:				
25-50 mg three or four times a day.	Your doctor will advise.	Your doctor will advise.	Your doctor will advise.	Your doctor will advise.
Nausea and Vomiting in Serious illness:				
10-25 mg every 4 to 6 hours.	Do not use unless the need is life-saving.	0.5 mg per kg bodyweight every 4 to 6 hours (up to 40 mg daily).	0.5 mg per kg bodyweight every 4 to 6 hours (up to 75 mg daily).	Initially one-third to one half the adult dose. The doctor will judge the amount needed for you.

Exposure to sunlight

Chlorpromazine can make your skin more sensitive to sunlight. Keep out of direct sunlight while having 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 capacity.

If you take more Chlorpromazine than you should

If you have taken more Chlorpromazine than you should, go to your doctor or nearest hospital casualty department **immediately**.

Having too much Chlorpromazine may make you feel drowsy or dizzy with increased or rapid heartbeat. You may also feel very cold and restless, with writhing movements, stiffness or shaking.

If you forget to take Chlorpromazine

If you miss a dose, take it as soon as you remember and take any remaining doses for that day at evenly spaced times.

Do not take a double dose to make up for the forgotten dose. Ignore the dose you missed and take it as soon as you remember and carry on as before.

If you stop taking Chlorpromazine

Do not stop taking Chlorpromazine without asking your doctor first. Your dose needs to be reduced gradually otherwise you may experience the following sudden withdrawal symptoms: feeling sick, vomiting, sweating, insomnia, recurrence of psychotic symptoms and involuntary movement disorders.

4. POSSIBLE SIDE EFFECTS

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

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

Very common (affects 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 (affects 1 to 10 people in 100 people)

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

Frequency unknown

- you have an allergic reaction. The signs may include: rash, itching, fever, difficulty in breathing or wheezing, chills, swollen eyelids, 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 'leukopenia'
- 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 vomiting or 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.

Other side effects

Tell a doctor as soon as possible if you have any of the following side effects:

Very common (affects more than 1 in 10 people)

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

Frequency unknown

- 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 to 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.

Talk to your doctor if any of the following side effects gets serious or lasts longer than a few days:

Very common (affects more than 1 in 10 people)

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

Common (affects 1 to 10 people in 100 people)

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

Frequency unknown

- 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
- body temperature problems.

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 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

Keep this medicine out of the sight and reach of children. Do not store above 25°C. Keep container in the outer carton.

Do not use this medicine after the expiry date which is stated on the label or carton.

The expiry date refers to the last day of that month.

Once opened, the solution must be used within one 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 contains

- The **active** ingredient is chlorpromazine hydrochloride 25 mg / 5 ml.
- The **other ingredients** are hydroxyethylcellulose, glycerol (E422), sorbitol (E420), hydrochloric acid, aspartame (E951), citric acid monohydrate, Sunset Yellow (E110), polysorbate 20, ethanol, star anise oil, sodium benzoate (E211), purified water.

What Chlorpromazine looks like and contents of the pack

Chlorpromazine is a clear orange coloured liquid, and is available in amber glass bottles of 100 ml, 150 ml and 200 ml.

Marketing Authorisation Holder

Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland

Manufacturer

Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland

or

CP Pharmaceuticals Ltd., Ash Road North, Wrexham, LL13 9UF, United Kingdom.

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