

PACKAGE LEAFLET: INFORMATION FOR THE USER

CHLORPROMAZINE 10 mg 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 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

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1. WHAT CHLORPROMAZINE IS AND WHAT IT IS USED FOR

Chlorpromazine belongs to a group of medicines called 'phenothiazines'. 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
- feeling or being sick, (where other anti-sickness medicines have not worked)
- hiccups
- autism

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CHLORPROMAZINE

Do not have take Chlorpromazine 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Chlorpromazine 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
- You have liver or kidney problems
- You have epilepsy or have had fits (seizures)
- You have Parkinson's disease
- You have thyroid problems
- You have heart problems or a family history of heart problems
- You have ever had a stroke
- You have a form of muscle weakness called 'myasthenia gravis'
- You have a tumour on the adrenal gland called 'phaeochromocytoma'
- You have low blood levels of potassium, calcium and magnesium. Your doctor may do blood tests to check on these
- You are diabetic or have high levels of sugar in your blood (hyperglycaemia). Your doctor may want to monitor you more closely
- You have an enlarged prostate gland
- You have depression
- You have ever had alcohol problems
- You have a low number of white blood cells (agranulocytosis). This means you may get infections more easily than usual
- You are elderly (65 years of age or older)
- You have had glaucoma (painful eyes with blurred vision)
- You are allergic to other phenothiazine medicines such as prochlorperazine or you suspect any allergic reaction while taking chlorpromazine
- You have low blood pressure or feel dizzy when you stand up
- You 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.

Skin reactions

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS), have been reported with the use of Chlorpromazine. 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

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.

Other medicines and Chlorpromazine

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 can affect the way some other medicines work. Also some medicines can affect the way Chlorpromazine works.

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 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.

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 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.

Chlorpromazine contains

- **Lactose:** This medicine contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to other phenothiazine medicines such as prochlorperazine or you suspect any allergic reaction while taking this medicinal product.
- **Sodium:** This medicine contains less than 1mmol sodium (23 mg) per tablet, that is to say essentially "sodium free".

3. HOW TO TAKE CHLORPROMAZINE

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

The recommended dose is:**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.

The tablet can be divided into equal doses.

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

If you take more Chlorpromazine 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

Do not take a double dose to make up for a forgotten dose. Skip the missed dose then continue as before.

If you stop taking Chlorpromazine

Keep taking Chlorpromazine until your doctor tells you to stop. If you stop taking Chlorpromazine 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 medicine 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:**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 and 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
- 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 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**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 package or container. The expiry date refers to the last day of that month.

Store below 25°C in a dry place and protect from light. Store in the original package or container and keep the container tightly closed.

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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION**What Chlorpromazine tablets contain**

The active substance is chlorpromazine hydrochloride. Each tablet contains 10 mg chlorpromazine hydrochloride.

The other ingredients are lactose monohydrate, maize starch, povidone k 30, sodium starch glycolate, colloidal anhydrous silica, magnesium stearate and opadry white 21S58740 (hypromellose (E464), ethylcellulose, diethyl phthalate, titanium dioxide (E171)).

What Chlorpromazine looks like and contents of the pack

Chlorpromazine tablets are white film-coated, biconvex, odourless, tablets, with a break line on one side and plain on the other side.

The tablets come in blister packs and containers of 28, 30, 50, 56, 60, 84, 100, 250, 500, 1000 and 5000 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

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For more information about this product, please contact the Marketing Authorisation Holder.

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