

Chlorpromazine Hydrochloride 100mg/5ml Oral Syrup

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.

What is in this leaflet:

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

1. What Chlorpromazine Syrup is and what it is used for

The name of your medicine is Chlorpromazine Hydrochloride 100mg/5ml Oral Syrup (referred to as Chlorpromazine Syrup in this leaflet). It contains chlorpromazine hydrochloride. This belongs to a group of medicines called neuroleptics.

Chlorpromazine acts on the brain to calm your emotions.

Chlorpromazine can be used to treat:

- schizophrenia
- feeling and being sick, when you have a terminal illness
- persistent hiccups
- schizophrenia and autism in children
- or to calm your emotions particularly if you feel anxious, agitated, over-excited, violent or dangerously impulsive.

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

Do not take Chlorpromazine Syrup and tell your doctor if:

- you are allergic (hypersensitive) to chlorpromazine or any other ingredients in this liquid (listed in section 6). The signs of allergic reaction can include a rash, itching or shortness of breath
- you are pregnant or breast-feeding
- you have a history of blood problems
- you have severe heart disease
- you have dulled senses such as feeling sleepy or uncoordinated, having blurred vision, slurred speech or being less aware of your surroundings (CNS depression).

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 Syrup.

Warnings and precautions.

Talk to your doctor before taking Chlorpromazine Syrup, if:

- you have heart problems including unusual heart beats, heart disease or heart failure
- you have lung and breathing problems
- you have kidney problems
- you have Parkinson's Disease
- you have or have had in the past narrow angle glaucoma (this is abnormal pressure in the eye accompanied by pain and blurred vision)
- you have an enlarged prostate gland
- you have epilepsy or have had epilepsy in the past
- you have a condition that causes muscle weakness with tiredness, called myasthenia gravis
- you have a tumour of your adrenal gland that causes high blood pressure (phaeochromocytoma)
- you have liver problems
- you have an underactive thyroid
- you are feeling depressed
- 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 had a stroke or you have any of the following that can increase your risk of having a stroke
 - a heart attack
 - a TIA (transient ischaemic attack). This is a type of stroke where symptoms last less than 24 hours
 - an artificial heart valve
 - uncontrolled high blood pressure
 - diabetes
 - high cholesterol
 - a family history of strokes
 - you smoke
 - you drink excess alcohol (this tends to weaken blood vessels and can raise blood pressure)
- Older people should take chlorpromazine with caution in very hot or cold weather. This is because there is a risk of having a higher body temperature than usual in hot weather (hyperthermia) and a lower body temperature in cold weather (hypothermia) if you take this medicine
- If you are having anaesthetic, tell your doctor or dentist that you are taking chlorpromazine.

Other important information to take into account before you take this medicine:

- if you or members of your family have heart problems (including heart failure, heart attack or uneven heart beats) or you have low potassium or magnesium in your blood, your doctor may do some tests on your heart and blood before giving you this medicine
- your doctor may also want to give you regular blood tests in the first few months of your treatment
- do not go into direct sunlight if you are taking high doses of this medicine. This is because you may become more sensitive to strong sunlight while taking this medicine
- do not put this medicine in contact with your skin as it may cause a skin problem called dermatitis (a skin rash with itching). If the medicine does have contact with your skin, wash the area thoroughly.

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

Other medicines and Chlorpromazine Syrup:

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.

Tell your doctor if you are taking any of these medicines:

- heart medicines such as quinidine, disopyramide, procainamide, amiodarone, sotalol, dofetilide, bretylium, calcium channel blockers such as verapamil, ACE inhibitors such as captopril
- medicines to treat high blood pressure such as propranolol, guanethidine, methyl dopa, metirosine, clonidine
- medicines that control your emotions such as anxiety medicines, antidepressants such as amitriptyline and maprotiline, pimozide, sertindole, haloperidol, lithium, trazodone
- medicines that help you sleep such as sedatives or hypnotics such as temazepam
- medicines to treat epilepsy such as barbiturates or phenytoin
- medicines used to treat malaria such as quinine and mefloquine
- antibiotics such as sparfloxacin, moxifloxacin and intravenous erythromycin
- medicines used to treat Parkinson's Disease such as levodopa, bromocriptine, lisuride and pergolide
- medicines to treat allergies such as hayfever (antihistamines) for example terfenadine and astemizole
- medicines to treat stomach problems such as cimetidine or cisapride
- medicines to treat diabetes
- strong painkillers such as codeine
- medicine used to treat cancer
- tetrabenazine, used to treat disorders that cause unnatural movements
- medicines that help the body get rid of water and affect electrolyte balance (diuretics) such as furosemide or indapamide
- prochlorperazine, used to treat nausea (feeling sick) and vomiting
- desferrioxamine, used to treat some types of anaemia, a type of blood problem
- phenylpropranolamine, used to treat a blocked stuffy nose
- adrenaline.

If you are taking antacids, you should take these at least two hours after taking chlorpromazine.

Chlorpromazine Syrup with food, drink and 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 even more drowsy. Drinking alcohol may also affect the condition you are suffering from.

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 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.

Driving and using machines:

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

Important information about what is in this medicine:

Chlorpromazine Syrup contains:

- ethanol (alcohol). This product contains a small amount of alcohol, less than 100mg per dose
 - methyl, ethyl and propyl parahydroxybenzoates. These may cause an allergic reaction. This allergy may happen some time after starting the medicine
 - sorbitol and sucrose. If your doctor has told you that you cannot tolerate some sugars, see your doctor before taking this medicine.
- In large doses it can have a laxative effect.
- The number of calories provided by sorbitol in the maximum daily dose is 36Kcal.
 - There are 2.25 grams of sucrose in each 5ml dose. You should take this into account if you have diabetes. It may be harmful to your teeth.

3. How to take Chlorpromazine Syrup

Always take this medicine exactly as your doctor or pharmacist has told you. Look on the label and check with your doctor or pharmacist if you are not sure.

Taking this medicine

- this medicine contains 100mg of chlorpromazine hydrochloride in each 5ml
- take this medicine by mouth
- if you feel that the effect of your medicine is too strong or too weak, do not change the dose yourself, but talk to your doctor or pharmacist.

Adults

- The usual dose for adults is 40mg to 300mg 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
- Older people will need to take one third or half the usual 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 40mg a day. You must split this dose over the day.
- Children aged 6 to 12 years: the maximum dose should be no more than 75mg 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 Syrup 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 quick and shallow breaths, low body temperature, low blood pressure, restlessness, twisting of your limbs, fits, unusual heart beats and coma.

If you forget to take Chlorpromazine Syrup

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

If you stop taking Chlorpromazine Syrup

Keep taking Chlorpromazine Syrup until your doctor tells you to stop. The doctor will lower your dose gradually.

If you stop taking the medicine suddenly you may get withdrawal symptoms. Signs include:

- feeling or being sick, sweating and difficulty sleeping (insomnia)
- your original symptoms becoming worse
- movements that you can't control.

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

4. Possible side effects

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

Stop taking the medicine straight away and see your doctor if:

- **you have an allergic reaction to chlorpromazine syrup**
An allergic reaction may include any kind of skin rash, flaking skin, boils or sore lips and mouth, sudden wheezing, fluttering or tightness of the chest or collapse
- **you have any of the following symptoms:**
 - unusually fast heart beat, unstable blood pressure (feeling dizzy, light-headed or faint) and sweating. These are early warning signs of a disorder caused by the type of medicine you are taking
 - very high body temperature, muscle stiffness or a change in consciousness leading to coma

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- a prolonged painful erection. If this happens to you, go to your nearest hospital
- yellowing of the skin and whites of your eyes (jaundice) with fever and possible liver damage.

If you get any of the following side effects, see your doctor as soon as possible:

- 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**
- feeling depressed, agitated, lack of emotion
- fits
- blood problems. You may notice signs such as high temperature or chills, sore throat, ulcers in your mouth or throat and unusual tiredness
 - heart changes including fast heart beats, unusual heart beats, heart attack. Symptoms of a heart attack are chest pain which may spread to the shoulders, neck or arms and shortness of breath. If you get these see a doctor straight away. Unexplained deaths have been reported but it is not proven that they were caused by chlorpromazine
 - low body temperature
- low blood pressure. You may feel dizzy when standing up. This may affect older people more
- unusual movements, often of the mouth, lips, eyes and tongue. These movements can also include trembling and shaking of the hands and feet, twisting of the body, shuffling walk and stiffness of the arms and legs and unable to sit still.
- eye changes, such as problems with your eyesight or change in eye colour
- hyperglycaemia (high levels of glucose in the blood). The symptoms of this are feeling thirsty, urinating more often and tiredness
- changes in bowel habits.

Tell your doctor if you get any of these side effects:

- unable to sleep, nightmares
- dry mouth, blocked nose
- pale skin
- skin rash caused by medicine spilt on your skin, skin rashes, skin reaction to direct sunlight
- swelling of the breasts (particularly in men) and breast milk production
- light periods or absence of periods
- decrease in sexual performance
- weight gain
- high cholesterol levels
- changes in your level of alertness.

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.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

5. How to store Chlorpromazine Syrup

- Keep this medicine out of the sight and reach of children
- Store below 25°C. Do not allow to freeze
- Take any unused medicine back to the pharmacy 6 months after you first open it
- Do not use this medicine after the expiry date which is stated on the label and carton (exp: month, year)
- The expiry date refers to the last day of that month
- Do not use this medicine if you notice that the appearance or smell of your medicine has changed. Talk to your pharmacist
- 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 Syrup contains

- The active ingredient is chlorpromazine hydrochloride
- The other ingredients are ascorbic acid (E330), sorbitol solution 70% (E420), sucrose, methyl hydroxybenzoate (E218), ethyl hydroxybenzoate (E214), propyl hydroxybenzoate (E216), propylene glycol (E1520), caramel (E150), apricot flavour, garden mint flavour, isopropyl alcohol and purified water.

What Chlorpromazine Syrup looks like and contents of the pack

A pale to dark red-brown syrup with an odour of apricot and mint.

It comes in a brown glass bottle holding 150ml of syrup.

Marketing Authorisation Holder and Manufacturer

Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

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