Rosemont®

Package leaflet: Information for the user

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, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- you have increased pressure in the eye (glaucoma)
- you are taking a dopaminergic antiparkinsonism drug
- you are taking citalopram for escitalopram
- you have a history of low white blood cell count
- you have urine retention due to a prostate disorder
- you are pregnant or breast-feeding
- you have a history of blood problems, including if you have a low number of white blood cells (bone marrow depression)
- 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 liver or kidney problems
- you have thyroid problems
- you have heart problems or a family history of heart problems
- you have ever had a stroke
- you have Parkinson's disease
- you have epilepsy or have had fits (seizures)
- you have depression
- you have ever had alcohol problems
- you have an enlarged prostate gland
- you have had glaucoma (painful eyes with blurred vision)
- you have a tumour on the adrenal gland called 'phaeochromocytoma'
- you have a form of muscle weakness called 'myasthenia gravis'
- you have a low number of white blood cells (agranulocytosis). This means you may get infections more easily than usual
- you have low blood levels of potassium, calcium and magnesium. Your doctor may do blood tests to check on these
- 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 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 not eating properly
- you are allergic to other phenothiazine medicines such as prochlorperazine, or you suspect any allergic reactions while taking chlorpromazine.
- you are elderly (65 years of age or older)
- you are elderly, particularly during very hot or very cold weather. In these conditions, you could be at risk of hyperthermia or hypothermia
- you have low blood pressure or feel dizzy when you stand up
- you are diabetic or have high levels of sugar in your blood (hyperglycaemia). Your doctor may want to monitor you more closely

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.

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, methyldopa, 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, phenytoin or phenobarbital
- 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, pergolide, amantadine, piribedil and ropinirole
- medicines to treat allergies such as hayfever (antihistamines) for example terfenadine and astemizole
- medicines for indigestion and heartburn (antacids)
- medicines to treat stomach problems such as cimetidine or cisapride
- medicines to treat diabetes
- medicines for high blood pressure or prostate problems such as doxazosin and terazosin
- 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
- amphetamines – used for Attention Deficit Hyperactivity Disorder (ADHD)
- anticholinergic medicines – includes some medicines used for irritable bowel syndrome, asthma or incontinence'
- 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 – used for life threatening allergic reactions
- lithium – used for some types of mental illness
- medicines that may interact in the metabolism of chlorpromazine; examples include ciprofloxacin, oral contraceptives.

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:

Talk to your doctor or nurse before having this medicine if you are pregnant, might become pregnant, or think you may be pregnant.

The following symptoms may occur in newborn babies, of mothers that have used chlorpromazine syrup 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 syrup. This is because small amounts may pass into mothers' milk. If you are breastfeeding 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 breastfeeding.

Chlorpromazine may make it more difficult for women 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 drowsy or if it has affected your eyesight.
Important information about what is in this medicine:
Chlorpromazine Syrup contains:
- Ethanol. This medicine contains 0.37mg of alcohol (ethanol) in each 5ml dose. The amount in 5ml of this medicine is equivalent to less than 1ml beer and 1ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.
- Methyl, Ethyl and Propyl parahydroxybenzoates (E218, E214, and E216). May cause allergic reactions (possibly delayed).
- Propylene Glycol (E1520). This medicine contains 83.73mg of propylene glycol in each 5ml dose.

Continued overleaf

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ARTWORK VERSION: 3 Date: 23.03.2023 Operator: EVA

PRINT VERSION: Date: Operator:

JOB INFORMATION

Product Name: Chlorpromazine Hydrochloride Oral Syrup

Strength: 100mg_5ml
Pack Size: 150ml
Bottle Size: 150ml
Design Icon: N/A

New Item Code: G3ND1RBJ3
Previous Item Code: G3ND1RBJ2
Supplier Code: N/A
Change Control No.: 00222

JOB SPECIFICATION

Keyline Ref: UKL413
Dimensions: 150 x 500mm
Folded Size: 150 x 33mm
Tabbed: NO

Pharmacode: 26
EAN Code:
No. of Colours: 1
Page Number: 1 of 2

MAIN BODY TEXT

Font Type: Univers Roman / Univers Bold
Font Size: 8 pt

COLOURS

Print Colours: Black

TECHNICAL NON PRINTING COLOURS

Keyline, Cirrus_Info_Box

APPROVALS

Third Party Approval: Name: Sign: Date:

Regulatory Approval: Name: Sign: Date:

- Sorbitol (E420). This medicine contains 455mg sorbitol in each 5ml dose. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
- Sucrose. 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 2.25g of sucrose in each 5ml dose. This should be taken into account in patients with diabetes mellitus. May be harmful to the 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, feeling drowsy or dizzy, 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.

Tell a doctor or nurse 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 a 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, lips, tongue or throat
- You have a very fast, uneven or forceful heartbeat (palpitations), heart attack. 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 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) have been reported with Chlorpromazine
- 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

Tell a nurse or 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 syrup 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 or nurse 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 a 100 people)
- Abnormal production of breast milk in men and women
- Loss of menstrual periods or light 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

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

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme: 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 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 (contains ethanol), garden mint flavour (contains propylene glycol), 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.

This leaflet was last revised in 03/2023

G3ND1RBJ3_V3

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APPROVALS

Third Party Approval

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Sign:
Date:

Regulatory Approval

Name:
Sign:
Date: