

**Package leaflet: Information for the user**  
**Chlorpromazine Elixir BP 25 mg/5 ml Oral 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 Elixir is and what it is used for
2. What you need to know before you take Chlorpromazine Elixir
3. How to take Chlorpromazine Elixir
4. Possible side effects
5. How to store Chlorpromazine Elixir
6. Contents of the pack and other information

**1. WHAT CHLORPROMAZINE ELIXIR IS AND WHAT IT IS USED FOR**

Chlorpromazine Elixir 25 mg/5 ml Oral Solution belongs to a group of medicines known as antipsychotics, which have a tranquillising effect, reducing anxiety and tension, stabilising mood swings and controlling aggression.

Chlorpromazine Elixir is used for:

- Management of anxiety, agitation, depression, behavioural disturbances, senile irritability
- Schizophrenia and other psychoses (loss of contact with reality) including mania (very high or very low moods)
- Terminal illness
- Uncontrollable hiccups
- Eclampsia and pre-eclampsia (in pregnancy)
- Pre and post-anaesthesia

**2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CHLORPROMAZINE ELIXIR**

**Do NOT take Chlorpromazine Elixir:**

- if you are allergic to chlorpromazine or any of the other ingredients of this medicine (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 dopaminergic antiparkinson drugs
- 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
- have a gluten allergy or intolerance.

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.

**Warning and precautions**

**Talk to your doctor before taking Chlorpromazine Elixir:**

- 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
- 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 'phaeochromocytoma'
- 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, particularly during very hot or very cold weather. 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 Elixir.

This medicine should be taken 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).

**Avoid any unnecessary contact with the skin. If you are taking high doses of Chlorpromazine Elixir you should avoid exposure to the sun as this may cause a skin rash or burning.**

**Children and adolescents**

This medicine should not be given to children under 1 year old and only given to children under 6 where exceptional circumstances exist. There is a potential risk to brain function, therefore children should undergo a yearly clinical examination to evaluate learning capacity.

**Other medicines and Chlorpromazine Elixir**

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.

**Chlorpromazine with alcohol**

Do not drink alcohol whilst being treated with Chlorpromazine Elixir. This is because alcohol can increase the effects of Chlorpromazine Elixir 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 Elixir. 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 Elixir 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 Elixir contains sucrose, sodium methyl hydroxybenzoate, sodium ethyl hydroxybenzoate, sodium propyl hydroxybenzoate, amaranth and tartrazine**

- **sucrose:** each 5 ml of Elixir contains 3.75 g of sucrose. This should be taken into account by patients with diabetes mellitus. May be harmful to teeth. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- **sodium methyl hydroxybenzoate** (E219), **sodium ethyl hydroxybenzoate** (E215) and **sodium propyl hydroxybenzoate** (E217) which may cause allergic reactions (possibly delayed)
- **amaranth** (E123) and **tartrazine** (E102) colouring agents which may cause allergic reactions (possibly delayed).

**3. HOW TO TAKE CHLORPROMAZINE ELIXIR**

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

DO NOT increase the dose unless told to do so by your doctor. If this medicine is for a child, make sure that the dose is given exactly as prescribed by the doctor.

DO NOT EXCEED THE DOSE PRESCRIBED BY YOUR DOCTOR.

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
<b>For schizophrenia, other psychoses (loss of contact with reality), anxiety and other mental disturbances:</b>				
Initially, 25 mg three times a day or 75 mg at bedtime. This may be increased by daily amounts of 25 mg by your doctor (usually 75 mg to 300 mg or to a maximum of 1 g daily).	Do NOT give.	0.5 mg/kg bodyweight every 4 to 6 hours up to a maximum of 40 mg daily.	Initially one-third to half the adult dose up to a maximum of 75 mg daily.	Initially one-third to one half the adult dose. This may be gradually increased by your doctor.
<b>Hiccup:</b>				
25-50 mg three times a day.	Your doctor will advise.	Your doctor will advise.	Your doctor will advise.	Your doctor will advise.
<b>Nausea and Vomiting in Serious illness:</b>				
10-25 mg every 4-6 hours.	Do NOT give.	0.5 mg/kg bodyweight every 4 to 6 hours (up to a maximum of 40 mg daily).	0.5 mg/kg bodyweight every 4 to 6 hours (up to a maximum of 75 mg daily).	Initially one-third to one half the adult dose. This may be gradually increased by your doctor.

#### Exposure to sunlight

Chlorpromazine Elixir 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/give more Chlorpromazine Elixir than you should

If you, or someone else, have taken too much medicine, contact your doctor immediately or go to your nearest hospital accident and emergency department. Take this leaflet and/or the pack with you.

Having too much Chlorpromazine Elixir 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/give Chlorpromazine Elixir

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 a forgotten dose.

#### If you stop taking Chlorpromazine Elixir

Keep having Chlorpromazine Elixir until your doctor tells you to stop. If you stop having Chlorpromazine Elixir 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.

### 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 '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 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.

#### 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL -Dublin 2: Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie), email: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

### 5. HOW TO STORE CHLORPROMAZINE ELIXIR

Keep out of the sight and reach of children. Do not store above 25°C. Keep the bottle in the original container. Do not use this medicine after the expiry date which is 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 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 Elixir contains:

- The **active** ingredient is chlorpromazine hydrochloride (25 mg per 5 ml solution).
- The **other ingredients** are sucrose, purified water, hydrochloric acid (for pH-adjustment), polysorbate, spearmint flavour and colours tartrazine (E102), amaranth (E123) and green S (E142). It also contains the preservatives sodium methyl hydroxybenzoate (E219), sodium ethyl hydroxybenzoate (E215) and sodium propyl hydroxybenzoate (E217). (see end of Section 2 for further information on the ingredients)

#### What Chlorpromazine Elixir looks like and contents of the pack

Chlorpromazine is an amber-brown coloured liquid with a spearmint odour and flavour and is available in amber glass bottles of 200 ml, 500 ml, 1 litre, 2 litre and 2.5 litre. Not all pack sizes may be marketed.

#### Marketing Authorisation Holder and Manufacturer

Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.  
PA 281/124/1

This leaflet was last updated in November 2017.

23LF01508PW