Package Leaflet: Information for the user

Chlorpromazine 25 mg Tablets
Chlorpromazine 50 mg Tablets
Chlorpromazine 100 mg Tablets

Active substance: Chlorpromazine Hydrochloride

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What Chlorpromazine is and what it is used for
2. Before you take Chlorpromazine tablets
3. How to take Chlorpromazine tablets
4. Possible side effects
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1. What Chlorpromazine is and what it is used for

Chlorpromazine belongs to a group of drugs known as antipsychotics, which act on the central nervous system.

Chlorpromazine tablets are used for:
- The treatment of behavioural disturbances, including schizophrenia, mania and hypomania
- The short-term treatment of anxiety, agitation and violent or impulsive behaviour
- The treatment of persistent hiccup and nausea and vomiting associated with terminal illness.

2. Before you take Chlorpromazine tablets

DO NOT TAKE Chlorpromazine tablets if you:
- Are allergic (hypersensitive) to
  - Chlorpromazine
  - Any of the other ingredients of Chlorpromazine tablets (see section 6 “Further information”)
- Have a low blood cell count (bone marrow depression)

Check with your doctor before taking Chlorpromazine tablets if you:
- Suffer from liver or kidney problems
- Suffer from epilepsy (fits)
– Have had, or any member of your family has had, any disease that has affected the heart or blood circulation
– Or someone else in your family has a history of blood clots, as medicines like this have been associated with formation of blood clots
– Have an underactive thyroid gland (hypothyroidism)
– Suffer from a physical disorder of the brain that causes decreased mental function, such as Parkinson’s disease
– Have a tumour of your adrenal gland
– Suffer from the condition myasthenia gravis (muscular weakness)
– Have prostate trouble
– Have had glaucoma (painful eyes with blurred vision)
– Suffer from any metabolic disorder such as low levels of calcium, magnesium or potassium in the blood
– Suffer from dehydration or have recently lost a lot of blood.

If you are to undergo surgery you should inform the surgeon and anaesthetist of your treatment with Chlorpromazine as the combined use of both anaesthetic and Chlorpromazine may decrease your blood pressure (low blood pressure).

As the medicine may make your skin more sensitive to the effects of the sun, you should avoid exposure to direct sunlight during treatment.

If you are elderly you may be more sensitive to the effects of Chlorpromazine tablets, particularly if you have had a stroke in the past, and during very hot or very cold weather, as there is a risk of hyperthermia (high body temperature) or hypothermia (low body temperature).

As Chlorpromazine can occasionally affect the heart, your doctor will arrange regular monitoring of your heart rhythm. As some of these effects can be made worse by lack of certain elements known as electrolytes in your blood, your doctor will also monitor these on a regular basis.

Your doctor may need to carry out regular blood tests during treatment with Chlorpromazine.

**Taking other medicines:**
Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

**Please consult your doctor if you are taking:**
– Barbiturates (sleeping drugs) and other sedatives
– Guanethidine and Clonidine (beta blocker medicines to control blood pressure)
– Captopril (ACE inhibitor medicine to control blood pressure)
– Prochlorperazine (medicine used to calm emotional and mental problems)
– Disopyramide, amiodarone and sotalol (medicines to control your heartbeat)
– Anticholinergic drugs, which affect the nervous system (e.g. atropine and hyoscine)
– Amphetamine (used to treat narcolepsy and attention deficit hyperactivity disorder)
– Adrenaline (used to treat cardiac arrest)
– Antacids (used to neutralise excess stomach acid)
– Medicines used to treat Parkinson’s disease (e.g. levodopa, carbidopa)
– Lithium (used for depression)
– Drugs used to treat diabetes (hypoglycaemic agents) such as Chlorpropamide, Glibenclamide, Tolbutamide.
– Desferrioxamine (used to treat iron poisoning)
– Tricyclic antidepressants (e.g. amitriptyline and imipramine)
– Medicines used for heart conditions (e.g. quinidine)
– Other medicines used to treat behavioural disturbances (e.g. thioridazine)
– Cimetidine (used to treat stomach ulcers)
– Metoclopramide (used to treat stomach upset)
– Sibutramine (used to treat obesity)
– Tetrabenazine (used to treat movement disorders)
– Ritonavir (used to treat HIV)
– Medicines used to treat pain (e.g. morphine and codeine) and anaesthetics
– Medicines used to treat epilepsy (e.g. phenytoin and carbamazepine)
– Antibiotics (used to treat infections) such as moxifloxacin

Taking Chlorpromazine tablets with food and drink:
You should avoid alcohol while taking this medicine as it may increase the sedative effects of Chlorpromazine.

Pregnancy and breast-feeding:
Tell your doctor if you are pregnant, think you might be pregnant or if you intend to become pregnant before you take Chlorpromazine tablets. Chlorpromazine should only be used during pregnancy if considered essential by your doctor.

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 take Chlorpromazine tablets while breast-feeding. Chlorpromazine is passed to your baby through your breast milk. If you have to continue treatment with Chlorpromazine tablets, you should stop breast-feeding.

Driving and using machines:
Chlorpromazine may cause drowsiness at the beginning of treatment. Do not drive or use machines if you are affected.

Important information about some of the ingredients of Chlorpromazine tablets:
This medicine contains lactose (milk sugar) and 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.

3. How to take Chlorpromazine tablets

Always take Chlorpromazine tablets exactly as your doctor has told you. You should check with your doctor if you are not sure. Your doctor will start you on a low dose to begin with. The dose will be gradually increased and your doctor will monitor you closely until a suitable dose is reached.

Adults:
- **Behavioural disturbances/anxiety:** Usually 25 mg three times daily or 75 mg at bedtime to start with. This may be increased by 25 mg a day to an effective dose. This is usually 75 – 300 mg daily, but some patients need up to 1000 mg (1g) daily.

- **Nausea and vomiting:** The usual dose is 10 – 25 mg every 4 to 6 hours.

- **Treatment of hiccup:** The usual initial dose is 25 – 50 mg every 6 to 8 hours.

**Elderly or debilitated:**

- **Behavioural disturbances/anxiety:** The usual starting dose is one third to one half the adult dose, with a more gradual increase in dosage.

- **Nausea and vomiting:** The usual starting dose is one third to one half the adult dose. If required your doctor may increase the dose.

**Children:**

- **Behavioural disturbances/anxiety:**
  - 1 – 5 years: 0.5 mg per kg of body weight every 4 to 6 hours. Do not exceed 40 mg daily.
  - 6 – 12 years: One third to one half the adult dose. Do not exceed 75 mg daily.

- **Nausea and vomiting:**
  - 1 – 5 years: 0.5 mg per kg of body weight every 4 to 6 hours. Do not exceed 40 mg daily.
  - 6 – 12 years: 0.5 mg per kg of body weight every 4 to 6 hours. Do not exceed 75 mg daily.

If this medicine is prescribed for a child make sure that the tablets are taken as stated on the pharmacist’s label.

Swallow the tablets with a drink of water. DO NOT CRUSH OR CHEW THE TABLETS.

**If you take more Chlorpromazine tablets than you should:**

Contact your doctor or pharmacist or telephone your nearest casualty department immediately. Remember to take the pack and any remaining tablets with you. The symptoms of overdose may include drowsiness or loss of consciousness, low blood pressure, irregular heartbeat, hypothermia (low body temperature) or involuntary movement.

**If you forget to take Chlorpromazine tablets:**

If you forget to take a dose, take it as soon as you remember. If your next dose is due within 2 hours, do not take the missed dose. Just take the next dose at the usual time.

**If you stop using Chlorpromazine tablets:**

Do not stop or change your treatment before talking to your doctor. Withdrawal symptoms can occur after you stop treatment, so gradual withdrawal is advisable. Withdrawal symptoms include feeling sick (nausea), being sick (vomiting), sweating, and difficulty sleeping.
(insomnia). Your illness may also come back and you may have movements that you cannot control, mainly of the tongue, mouth, jaw, arms and legs.

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

### 4. Possible side effects

Like all medicines, Chlorpromazine tablets can cause side effects, although not everyone gets them.

If you experience any of the following **STOP** taking this medicine and contact your doctor **IMMEDIATELY:**
- Skin rash
- Yellowing of the skin or whites of the eyes (jaundice)
- Unexplained sore throats, infections or fever (very high body temperature)
- Abnormal muscle movement (including those of the face, tongue, hands or legs)
- Low blood pressure (you may experience dizziness or fainting), rapid heartbeat or abnormal heart rhythm
- Breathing difficulties or swelling of the lips, face tongue or throat
- Respiratory depression (decreased rate and depth of breathing)
- A prolonged painful erection
- Sensitivity to sunlight
- Blood clots in the veins especially in the legs (symptoms including 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.

A side effect that occurs **very rarely** is neuroleptic malignant syndrome (NMS). The symptoms of NMS include high temperature, rigid muscles, rapid heart beat, incontinence, sweating, low blood pressure, confusion and drowsiness. If you experience any of these symptoms stop taking this medicine and **contact your doctor immediately.**

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.

**Common side effects** of Chlorpromazine are nasal stuffiness, dry mouth, difficulty sleeping, agitation and drowsiness, especially at the start of treatment.

If you experience any of the following side effects **tell your doctor:**
- Muscle stiffness or shaking, usually occurring after weeks or months of treatment
- An urge to move constantly (this may occur after large starting doses)
- Inability to control certain muscles in your body, including your tongue, mouth, arms and legs (this usually occurs after prolonged or high doses and may occur after treatment has stopped)
- Feeling unusual in very warm or very cold weather
- Difficulty focusing or loss in eyesight, which may occur after continuous long-term treatment
- Dizziness when standing up, especially if you are elderly
– Enlarged breasts and impotence in men
– Milk production in non breast-feeding women and absence of menstrual periods
– Facial rash, painful joints and feeling generally unwell and tired
– Discolouration (such as metallic greyish light purple colour) or irritation of the skin, (if tablets are crushed avoid contact with the skin).

If you are taking Chlorpromazine tablets for a long period of time, your doctor may want to do occasional tests, which might include an ECG to check that your heart is working normally, and a blood test.

If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, tell your doctor or pharmacist.

5. How to store Chlorpromazine tablets

Store below 25°C.

Store in the original tablet container.

Keep out of reach and sight of children.

Do not use Chlorpromazine tablets after the expiry date stated on the label. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Chlorpromazine tablets contain:
The active substance is Chlorpromazine hydrochloride. The tablets also contain, lactose monohydrate, povidone, magnesium stearate, maize starch, polyvinyl acetate phthalate, stearic acid, talc, calcium carbonate, acacia, sucrose, yellow carnauba wax, white beeswax, shellac, titanium dioxide (E171).

Each coated tablet contains 25 mg, 50 mg or 100 mg Chlorpromazine.

What Chlorpromazine tablets look like and contents of the pack:
Chlorpromazine 25 mg, 50mg and 100 mg tablets are white, circular, biconvex, sugar coated, unprinted tablets.

Chlorpromazine tablets are available in packs containing 25, 28, 50, 56, 100, 250, 500 or 1,000 tablets.

Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer:
This leaflet was last approved in November 2011