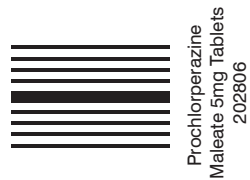


# Prochlorperazine Maleate 5mg Tablets Leaflet



Talk to your doctor or pharmacist if any of the side effects gets serious or lasts longer than a few days or if you notice any side effects not listed in this leaflet.

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.

**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](http://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 PROCHLORPERAZINE TABLETS**

Keep out of the reach and sight of children

Do not store above 25 °C. Store in the original package

Do not remove the medicine form the blister until you are ready to take the medicine

Do not use Prochlorperazine Tablets after the expiry date stated on the blister and carton, after EXP. The expiry refers to the last day of the month

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

**6. FURTHER INFORMATION**

**What Prochlorperazine Tablets contains**

Each tablet contains 5 mg of the active substance, Prochlorperazine Maleate.

The other ingredients are Lactose Monohydrate, Maize Starch, Colloidal Anhydrous Silica, Magnesium Stearate

**What Prochlorperazine Tablets look like and contents of the pack**

Prochlorperazine Maleate 5mg Tablets are white to off white coloured, circular shaped rounded tablets, with monogram P5 on one side and plain on the other side.

Prochlorperazine Maleate 5mg Tablets are available in blister packs containing 28 and 84 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder :**

**Rudipharm Limited**  
Unit 6, Salbrook Road Industrial Estate  
Salbrook Road, Redhill, Surrey,  
RH1 5GJ, United Kingdom.

**Manufacturer:**  
**Mobius Laboratories Limited**  
Unit 7, Bourne End Mills, Upper Bourne End Lane  
Hemel Hempstead, Hertfordshire, HP1 2UJ,  
United Kingdom.

**To listen to or request a copy of this leaflet in Braille, large print or audio please call, 01293 827819 (UK only)**

**Please be ready to give the following information:**

Product Name	Reference Number
Prochlorperazine 5mg Tablets	PL 49565/0074

**This leaflet was last revised in October 2023.**

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**Prochlorperazine Maleate 5 mg Tablets**

**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 any further questions, 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, tell your doctor or pharmacist

**In this leaflet:**

1. What Prochlorperazine Tablets are and what they are used for
2. Before you take Prochlorperazine Tablets
3. How to take Prochlorperazine Tablets
4. Possible side effects
5. Storing Prochlorperazine Tablets
6. Further information

**1. WHAT PROCHLORPERAZINE TABLETS ARE AND WHAT THEY ARE USED FOR**

Prochlorperazine maleate belongs to a group of medicines called ‘phenothiazine antipsychotics’.

It works by blocking the effects of a chemical in the brain.

Prochlorperazine can be used to:

- treat balance problems or dizziness (vertigo). This includes problems of the inner ear such as ‘Meniere’s Syndrome’ or ‘labyrinthitis’
- stop you feeling sick (nausea) or being sick (vomiting). This can be from any cause including migraines
- treat anxiety in the short-term, when used in addition to other medicines
- treat schizophrenia
- treat over-active behaviour or thoughts (mania)

**2. BEFORE YOU TAKE PROCHLORPERAZINE TABLETS**

**Do not take this medicine and tell your doctor if:**

You are allergic (hypersensitive) to prochlorperazine maleate or any of the other ingredients of Prochlorperazine Tablets (listed in Section 6 below)

Signs of an allergic reaction include; a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

**Take special care with Prochlorperazine Tablets Check with your doctor or pharmacist before taking your medicine if:**

- You are allergic to phenothiazine medicines such as chlorpromazine
- You have heart problems or a family history of heart problems
- You have ever has a stroke
- You have an enlarged prostate gland. This means you may have problems when passing water (urine)
- 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 Parkinson’s disease
- You have epilepsy or have ever had fits (seizures)
- You have a tumour on your adrenal gland called ‘phaeochromocytoma’
- You have a type of muscle weakness called ‘myasthenia gravis’
- You have or have ever had glaucoma (signs include painful eyes with blurred vision)
- You have or have ever had a low number of white blood cells (agranulocytosis). This would lead you to get infections more easily than usual
- You have low blood levels of potassium, calcium and magnesium. Your doctor may perform blood tests to check on these
- You are not eating properly or are very under-weight
- You have a history of alcohol problems
- You are diabetic or have high levels of sugar in your blood (hyperglycaemia). Your doctor may want to monitor you more closely.
- You have liver or kidney problems or have ever had jaundice (yellowing or the skin or whites of the eyes)
- You have an underactive thyroid gland
- You suffer with dementia
- You suffer from depression
- This person is a child. This is because children may develop unusual face and body movements (dystonic reactions)
- You are elderly (65 years of age or older). Prochlorperazine tablets should be used with caution during very hot or very cold weather to reduce the risk of an extreme rise or fall in body temperature

**If any of these points apply to you, do not take this medicine until you have talked to your doctor.**

**Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Prochlorperazine Tablets can affect the way some other medicines work.

**Note:** Position of the Pharma code will be changed as per Folding m/c requirement



Also some medicines can affect the way Prochlorperazine Tablets works.

In particular, tell your doctor if you are taking any of the following:

- antibiotics (medicines used to treat infections)
- cytotoxic (medicines used to treat cancer)
- antacids (medicines used for indigestion and heartburn) or kaolin preparations
- medicines to treat depression such as lithium or tricyclics (eg amitriptyline, dosulepin, imipramine)
- medicines to treat diabetes (eg chlorpropamide, gliclazide)
- medicines to treat high blood pressure (eg clonidine, doxazosin, guanethidine, nifedipine, verapamil),
- medicines to treat Parkinson's disease and some mental illnesses such as bromocriptine, cabergoline, levodopa, bpramipexole, ropinirole, apomorphine, lisuride, pergolide, pramipexole, amfetamine
- anticholinergics eg atropine sulphate, oxybutynin (included some medicines used for irritable bowel syndrome, asthma or incontinence)
- medicines used to treat anxiety and difficulty sleeping (eg diazepam, chlordiazepoxide)
- sotalol (to prevent and treat some heart conditions)
- desferrioxamine (to treat iron poisoning in the blood)
- sibutramine (used for weight loss)
- adrenaline e.g. epinephrine (used for life threatening allergic reactions)
- amphetamine (treatment for Attention Deficit Hyperactivity Disorder (ADHD))
- antipsychotics (e.g. chlorpromazine, trifluoperazine)
- medicines to treat epilepsy (e.g. phenobarbital, carbamazepine)
- medicines to treat irregular heart beat (e.g. amiodarone, flecainide, disopyramide, propranolol or quinidine)
- if you are about to undergo surgery or dentistry where an anaesthetic will be used
- ritonavir (for HIV infection)
- cimetidine (to treat stomach ulcers)
- strong pain killers (e.g. morphine, codeine phosphate)
- antihistamines, medicines used to treat allergies (e.g. terfenadine)

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

**Taking Prochlorperazine Tablets with food and drink**

Do not drink alcohol while you are taking Prochlorperazine Tablets. This is because alcohol can add to the effects of Prochlorperazine Tablets and can cause serious breathing difficulties.

**Pregnancy and breast-feeding**

This medicine is not recommended for women who are pregnant or breast-feeding. If you are pregnant, planning to become pregnant or are breastfeeding ask your doctor or pharmacist for advice before taking any medicine.

The following symptoms may occur in newborn babies, of mothers that have used prochlorperazine tablets 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**

Prochlorperazine tablets may cause drowsiness. Make sure you are not affected before you drive or operate machinery.

**Important information about some of the ingredients of Prochlorperazine Tablets**

- **Lactose:** This medicine contains lactose, a type of sugar. If you have been told by your doctor that you can not tolerate some sugars, talk to your doctor before taking Prochlorperazine Tablets.

**3. HOW TO TAKE PROCHLORPERAZINE TABLETS**

Always take Prochlorperazine tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

Swallow the tablets with water. Do not handle the tablets more than you need to as you may develop sore, red or blistered skin.

**Doses**

**Adults:**

**Dizziness (Vertigo):**

5mg three times a day, up to a maximum of 30mg a day. Your doctor may gradually reduce to 5-10mg a day after several weeks.

**Nausea and vomiting:**

Prevention: 5-10mg two or three times a day.

Treatment: 20mg immediately, followed if necessary by 10mg two hours later.

**To help with the treatment of anxiety:**

15-20mg a day (divided throughout the day). Up to a maximum of 40mg a day (divided throughout the day)

**Elderly:** Your doctor may prescribe a lower dose.

**Children:** Not recommended to children under 12 years of age.

**If you take more Prochlorperazine tablets than you should**

If you take too many tablets or a child swallows some, see your doctor immediately or contact the accident and emergency department of the nearest hospital. Take the medicine pack with you. This is so the doctor knows what you have taken. Taking too much Prochlorperazine may cause symptoms such as feeling sleepy or dizzy, increased or rapid heartbeat, feeling very cold and confused, writhing movements, feeling restless, stiffness or shaking. You may lose consciousness.

**If you forget to take Prochlorperazine Tablets**

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Prochlorperazine Tablets**

Keep taking Prochlorperazine Tablets until your doctor tells you to stop. Do not stop taking the tablets just because you feel better. If you stop, your illness may come back and you may have other effects such as feeling or being sick or difficulty sleeping. Your doctor will gradually stop your medicine to prevent these effects happening.

**Exposure to sunlight**

Prochlorperazine Tablets can cause your skin to be more sensitive to sunlight. Avoid exposure to direct sunlight while taking this medicine.

**Tests**

Your doctor may do regular tests while you are taking this medicine. These might include blood tests and an ECG to check your heart is working properly.

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

**4. Possible side effects**

Like all medicines, Prochlorperazine maleate Tablets can cause side effects, although not everybody gets them.

**Stop taking Prochlorperazine maleate Tablets and see a doctor or go to a hospital straight away if:**



- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You have an unusually pale complexion, sweating, high temperature, fast heartbeat, stiff muscles, fast breathing and feel confused, drowsy or agitated. These could be signs of a serious side effect called neuroleptic malignant syndrome'
- You have frequent infections such as fever, sore throat or mouth ulcers. These could be signs of a blood problem called leucopenia
- You may get infections more easily than usual. This could be because of a blood disorder (agranulocytosis)
- You have yellowing of your skin or eyes (jaundice). These could be signs of liver problems.
- You have very fast, uneven or forceful heartbeats (palpitations) and experience breathing problems such as wheezing, shortness of breath, tightness in the chest and chest pain
- 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 your doctor as soon as possible if you have any of the flowing side effects:**

- Breathing problems
- Changes in your skin or eye colour after taking Prochlorperazine Tablets for a long period of time
- Problems with your eyesight after taking Prochlorperazine Tablets for a long period of time
- Feeling dizzy, lightheaded or faint when you stand or sit up quickly (due to low blood pressure)
- Rigid or stiff muscles, trembling or shaking, difficulty moving, or loss of muscle power
- 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)

**Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days**

- Abnormal production of breast milk in men and women
- Breast enlargement in men
- Loss of menstrual periods
- Difficulty in getting or maintaining an erection (impotence)
- Difficulty sleeping (insomnia)
- Feeling restless or agitated
- Dry mouth
- Your skin being more sensitive to the sun than usual
- Stuffy nose
- Skin rashes
- Skin redness, swelling and itching from touching the medicine

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Packaging Material	Pil		Reason for Change	New Artwork Development	
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Carton/ Label	----		Pharmacode	527	Code No.: DRUGS/AP/14/2003
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	CHECKED BY (SKPL-PKG.DEV)	REVIEWED BY (SKPL-PROD/MFG)	REVIEWED BY (SKPL-RA)	APPROVED BY (SKPL-QA)	
SIGN/ DATE					