

Package leaflet: Information for the user**Prochlorperazine 5 mg Tablets
(Prochlorperazine maleate)****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. See section 4.

What is in this leaflet:

1. What Prochlorperazine Tablets are and what they are used for
2. What you need to know before you take Prochlorperazine Tablets
3. How to take Prochlorperazine Tablets
4. Possible side effects
5. How to store Prochlorperazine Tablets
6. Contents of the pack and other information

1. What Prochlorperazine Tablets are and what they are used for

Prochlorperazine Tablets contain a medicine called Prochlorperazine maleate. This belongs to a group of medicines called 'phenothiazine antipsychotics'. It works by blocking the effects of a chemical in the brain. Prochlorperazine Tablets 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 schizophrenia
- Treat over-active behaviour or thoughts (mania)
- Treat anxiety in the short-term, when used in addition to other medicines

2. What you need to know before you take Prochlorperazine Tablets**Do not take this medicine and tell your doctor if:**

- You are allergic (hypersensitive) to prochlorperazine, phenothiazine medicines such as chlorpromazine or any of the other ingredients of Prochlorperazine Tablets (listed in Section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

Warnings and Precautions

Talk to your doctor or Pharmacist before taking Prochlorperazine Tablets if:

- You have heart problems or a family history of heart problems
- You have ever had a stroke
- You have liver or kidney problems
- You have thyroid problems
- 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 dementia
- You have epilepsy or have ever had fits (seizures)
- You have depression
- 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 elderly (65 years of age or older)
- The person is a child. This is because children may develop unusual face and body movements (dystonic reactions)
- 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 Prochlorperazine Tablets

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.

Other Medicines and Prochlorperazine Tablets

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

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

- Medicines to help you sleep (sedatives, barbiturates)
- Other medicines used to calm emotional and mental conditions
- Medicines used for depression, including amitriptyline.
- Medicines used for Parkinson's disease such as levodopa
- Medicines for fits (epilepsy) such as carbamazepine
- Medicines used to control your heartbeat such as amiodarone, disopyramide, propranolol or quinidine
- Medicines for high blood pressure such as doxazosin, terazosin, guanethidine or clonidine
- Medicines used for diabetes
- Medicines used for cancer (cytotoxics)
- Medicines used for infections (antibiotics)
- Medicines for indigestion and heartburn (antacids)
- Anticholinergic medicines - includes some medicines used for irritable bowel syndrome, asthma or incontinence
- Amphetamines - used for Attention Deficit Hyperactivity Disorder (ADHD)
- Adrenaline - used for life threatening allergic reactions
- Desferrioxamine - used when you have too much iron in your blood
- Lithium - used for some types of mental illness

Prochlorperazine Tablets with food, drink and alcohol

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

Do not take Prochlorperazine Tablets if

- You are pregnant, think you might be pregnant or are planning to have a baby.
- You are breast-feeding or planning to breast-feed

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.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

You may feel sleepy after taking this medicine. If this happens, do not drive or use any tools or machines.

Prochlorperazine Tablets contain Lactose

This medicine contains lactose, a type of sugar.

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking Prochlorperazine Tablets

3. How to take Prochlorperazine Tablets

Always take this medicine exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure. The number of tablets you need will depend on your condition. The tablets should be swallowed whole with a small glass of water.

Taking this medicine

- Take this medicine by mouth
- Do not give to children under 1 year of age or who weigh less than 10 kg
- You should not let the tablets touch your skin for very long, as you may get skin redness, swelling and itching (contact skin sensitisation)
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

How much to take**Adults:****Treatment of balance problems or dizziness (Vertigo):**

- The usual dose is 5 mg three times each day
- This may be increased to a total daily dose of 30 mg each day
- After several weeks treatment, your doctor may decide to gradually lower your daily dose to 5 to 10 mg each day

Stopping you feeling sick or being sick:

- The usual dose is 5 or 10 mg. This may be taken two or three times each day

Treatment of feeling sick or being sick:

- To begin with you will usually take 20 mg
- This may be followed by 10 mg two hours later

Adults**Treatment of schizophrenia and overactive behaviour or thoughts (mania):**

- The starting dose is usually 12.5 mg twice each day for seven days
- Your doctor may increase your dose up to a total daily dose of 75 to 100 mg each day
- After several weeks of treatment, your doctor may then lower your dose to a total daily dose of 25 to 50 mg each day

Short-term treatment of anxiety:

- The starting dose will be 15 to 20 mg each day in divided doses
- Your doctor may then increase your dose to a total daily dose of 40 mg each day

Elderly:

- Your doctor may prescribe a lower dose
- You should be careful during very hot or very cold weather to make sure that you do not get too hot or too cold.

Children (over 1 year of age and weighing more than 10 kg):**Stopping your child feeling sick or being sick:**

- Your doctor will decide the dose according your child's weight
- A dose of 0.25 mg for each kilogram of your child's weight is usually given
- This dose may be given two or three times a day

If you take more Prochlorperazine Tablets than you should

If you take more Prochlorperazine Tablets than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. Taking too much Prochlorperazine Tablets 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 Prochlorperazine 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. You should avoid exposure to direct sunlight while taking this medicine.

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

4. Possible side effects

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

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

- You have serious allergic reactions. The signs may include: hives (itchy 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
- You have rigid or stiff muscles, trembling or shaking, unusual eye movements (including rolling of the eyes), difficulty moving, or loss of muscle power

Tell your doctor as soon as possible if you have any of the following 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)
- You have fits (convulsions)
- 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 (hyponatraemia)
- Feeling unwell, confused and/or weak, feeling sick (nausea), loss of appetite, feeling irritable. This could be something called a syndrome of inappropriate anti-diuretic hormone secretion (SIADH)
- 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

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.

As with other phenothiazine medicines, there have been very rare reports of sudden death with Prochlorperazine Tablets. These are possibly caused by heart problems.

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 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 Website: 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 this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date (EXP) which is stated on the carton. The expiry date refers to the last day of that month.
- Store below 25°C. Store in the original package.
- 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 Prochlorperazine Tablets contain**

Each tablet contains 5mg Prochlorperazine maleate as the active substance.

The other ingredients are lactose monohydrate, silica colloidal anhydrous, maize starch and magnesium stearate.

What Prochlorperazine Tablets look like and contents of the pack

Prochlorperazine 5mg tablets are white to off white circular, uncoated tablets with '5' debossed on one side. Prochlorperazine Tablets come in packs containing blister strips of 14 tablets (14, 28, 56 or 84 tablets in total). Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Name and Address:

Bristol Laboratories Ltd,
Unit 3, Canalside,
Northbridge Road, Berkhamstead,
Hertfordshire, HP4 1EG, UK
Telephone: 0044 (0)1442 200 922
Fax: 0044 (0)1442 873 717
E-mail: info@bristol-labs.co.uk

Manufacturer

Bristol Laboratories Ltd
Laporte Way, Luton, LU4 8WL,
United Kingdom

Prochlorperazine 5mg Tablets; PL 17907/0072**This leaflet was last revised in November 2022**

To request a copy of this leaflet in Braille, large print or audio format then please contact the licence holder at the address (or telephone, fax, email) above.