

Blooms The Chemist Prochlorperazine

Prochlorperazine maleate

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about prochlorperazine. It does not contain all the available information that is known about this medicine. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you using this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is Bloom the Chemist Prochlorperazine. It contains prochlorperazine maleate.

Prochlorperazine is used to treat nausea associated with migraine (throbbing headache, usually affecting one side of the head and often accompanied by nausea, vomiting, dizziness due to various causes, including migraine (severe headache) and sensitivity to light).

It belongs to a group of medicines called phenothiazines. It helps to correct imbalances in the brain,

allowing it to function correctly. These chemicals may also affect the parts of the brain which control nausea (feeling sick) and vomiting

This medicine is available in packs of 5 or 10 tablets from your pharmacist.

Ask your doctor or pharmacist if you have any questions why this medicine has been recommended for you.

Your doctor or pharmacist may have recommended it for another reason.

This medicine is not addictive.

There is not enough information to recommend the use of this medicine for children under the age of 18 years.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- prochlorperazine
- the group of medicines called phenothiazines
- any of the ingredients listed at the end of this leaflet

Some symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty in breathing

- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine if you have any of the following medical conditions:

- shock
- disease of the blood with a low number of blood cells
- yellowing of the skin and/or eye, also called jaundice

Do not take this medicine after the expiry date printed on the pack, if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should take this medicine, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor or pharmacist if you have or have had any of the following medical conditions:

- pheochromocytoma, a rare tumour of the adrenal glands which sit near the kidneys.
- Parkinson's disease, a disease of the brain affecting movement which causes trembling, rigid posture, slow movement and a shuffling, unbalanced walk
- myasthenia gravis, a disease of the muscles causing drooping

eyelids, double vision, difficulty in speaking and swallowing and sometimes muscle weakness in the arms or legs

- kidney or liver disease
- constipation
- heart and blood vessel problems, or a family history of these problems, including stroke, blood clots, low blood pressure
- prostate problems
- bowel problems
- epilepsy, seizures or fits
- low blood calcium levels
- thyroid problems
- glaucoma, a condition in which there is a build-up of fluid in the eye
- neuroleptic malignant syndrome, a reaction to some medicines with a sudden increase in body temperature, extremely high blood pressure and severe convulsions
- tardive dyskinesia, a reaction to some medicines with uncontrollable twitching or jerking movements of the arms and legs
- dementia
- diabetes
- a low number of white blood cells

Tell your doctor or pharmacist if you are pregnant, plan to become pregnant or are breastfeeding.

Prochlorperazine is not recommended for use during pregnancy and breast feeding. Your doctor and pharmacist will discuss with you the benefits and risks of using it.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking this medicine.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other

medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and prochlorperazine may interfere with each other. These include:

- some medicines used to control depression or mood swings or mental illness such as lithium.
- medicines metabolised by CYP2D6 (e.g. amitriptyline)
- alcohol
- desferrioxamine, a medicine used in iron overdose
- procarbazine, an anticancer drug
- some medicines used to control epilepsy such as phenobarbital and carbamazepine
- antibiotics used to treat infections
- atropine, a medicine which may be used in some eye drops or cough and cold preparations.
- some medicines used to prevent blood from clotting
- antacids containing magnesium, aluminium and calcium salts, oxides and hydroxides.
- Adrenaline used for severe allergic reactions
- amfetamine
- medicines used to treat high blood pressure or heart problems such as clonidine, guanethidine and propranolol and fluid build-up in your body
- medicines used to treat a fast or irregular heart beat e.g. amiodarone, quinidine, disopyramide
- medicines that can slow your heart beat e.g. diltiazem, verapamil.
- medicines that can reduce potassium levels in the blood e.g. diuretics, laxatives.
- other medicines that can affect your heart rate e.g. methadone, pentamidine.
- medicines to help you sleep
- other medicines used to calm emotional and mental conditions

- medicines used for Parkinson's disease (e.g. levodopa)
- medicines used for the treatment of diabetes
- propranolol, a medicine used to treat high blood pressure or prevent migraine headaches
- anticholinergic medicines used for stomach cramps, spasms and travel sickness, treat Parkinson's disease or incontinence.

These medicines may be affected by prochlorperazine or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking this medicine.

How to take this medicine

Follow all directions given by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Adults 18 years and over

For the treatment of nausea associated with migraine, take one or two tablets with water, two or three times a day if necessary or as advised by your pharmacist or doctor.

Do not use in children under 18 years of age.

How to take it

Swallow the tablets whole with a full glass of water. Do not chew the tablets.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of overdose may include the following:

- coma
- restlessness, shaking, muscle twitching, muscle weakness, spasm
- confusion
- excitement or agitation
- low blood pressure
- fast heart beat
- decrease in body temperature
- small pupils in the eye
- difficulty in swallowing or breathing
- blue skin

While you are taking this medicine

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Tell your doctor immediately if you notice any symptoms of tardive dyskinesia, including uncontrolled movements of the tongue, face, mouth or jaw, such as puffing of the cheeks, puckering of the mouth or chewing movements.

These are symptoms of a very rare condition called Tardive Dyskinesia, which may develop in some people taking phenothiazine medicines, including prochlorperazine.

These rare symptoms are more likely to occur during long term treatment with prochlorperazine, especially in elderly women.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you experience the following symptoms of neuroleptic malignant syndrome:

- sudden increase in body temperature
- stiff muscles
- fast heart beat
- altered mental state
- excessive sweating
- difficulty in breathing

Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not take this medicine to treat any other condition unless your doctor or pharmacist tells you to.

If you are about to be started on any new medicines, tell your doctor, dentist or pharmacist that you take this medicine.

If you are planning to have surgery that needs a general anaesthetic tell your doctor or dentist that you are taking this medicine.

Things to be careful of

Be careful while driving or operating machinery until you

know how this medicine affects you.

Prochlorperazine may cause dizziness, light-headedness, tiredness, blurred vision, drowsiness in some people.

Make sure you know how you react to this medicine before you drive a car, operate machinery, or do anything else that could be dangerous if you are tired, drowsy, dizzy or light-headed. If this occurs do not drive. If you drink alcohol, drowsiness, dizziness or light-headedness may be worse.

If this medicine makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position. Getting up slowly may help.

Combining this medicine and alcohol can make you more sleepy, dizzy or light-headed. Be careful when drinking alcohol while taking this medicine.

Your doctor or pharmacist may suggest you avoid alcohol while you are being treated with this medicine.

If outdoors, wear protective clothing and use at least a 15+ sunscreen.

Prochlorperazine may cause your skin to be much more sensitive to sunlight than it is normally, causing symptoms of a skin rash, itching, redness, or even severe sunburn. Tell your doctor if this occurs.

Make sure you keep cool in hot weather and keep warm in cool weather.

Prochlorperazine may affect the way your body reacts to temperature changes.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine.

Prochlorperazine helps most people with nausea associated with migraine, but it may have unwanted side effects in a few people. All

medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

If you are over 65 years of age you may have an increased chance of getting side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you.

- constipation
- dry mouth
- drowsiness
- restlessness
- trembling, rigid posture, mask-like face, slow movements and a shuffling unbalanced walk
- uncontrolled twitching, jerking or writhing movements.
- blurred vision

The following side effects are less common:

- low blood pressure
- changes in heart beats
- swelling of the hands, ankles or feet
- skin rash
- for females: unusual secretion of breast milk, irregular periods
- for males: breast enlargement, difficulty in ejaculating, getting or maintaining an erection, or persistent painful erection.
- Severe pain in the stomach with bloating, cramps and vomiting
- difficulty passing urine
- yellowing of the skin and/or eyes
- headache
- insomnia
- seizures
- agitation
- dizziness

- difficult in breathing
- brownish deposits in the eyes
- stuffy nose

Serious side effects-

Allergic reaction related:

- shortness of breath, wheezing or difficulty in breathing or swallowing
- swelling of the face, lips, throat, tongue or other parts of the body
- rash, itching or hives on the skin

Musculoskeletal related:

- unusual muscle tone or spasms causing distortion of the body in children

Other-

- sudden increase in body temperature, extremely high blood pressure and severe convulsions
- hypersensitivity, fever, rash, facial swelling, swollen lymph nodes (which could be symptoms relating to raised levels of infection fighting cells (relating to eosinophilia)
- Nervous system related: high fever, muscle cramps or stiffness, dizziness, severe headache, fast heartbeat, confusion, agitation, hallucination, or are sweating a lot (symptoms relating to Neuroleptic malignant syndrome).
- Liver related: yellowing of the skin and /or eyes (jaundice) and urine becomes darker in color
- Blood related: bleeding and bruising (thrombocytopenic purpura)

Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these side effects. These are very serious side effects. You may need urgent medical attention or hospitalisation.

See “Things you must do” for more information on side effects.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you

notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking this medicine

Storage

Keep the tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C. Protect from light.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one and-a-half meters above the ground is a good place to store medicines.

Disposal

If you stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

White to off-white tablets, round and marked with "5". Pack sizes of 5 or 10 tablets. AUST R 306575.

Ingredients

Each tablet contains 5mg prochlorperazine maleate as the active ingredient.

It also contains the following:

- lactose monohydrate

- maize starch
- colloidal anhydrous silica
- magnesium stearate
- purified water

The medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes. This medicine contains sugars as lactose

Sponsor

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