

Amcal Prochlorperazine

Contains the active ingredient, prochlorperazine (as maleate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Amcal 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 he/she expect it will have for you.

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

Keep this leaflet with your medicine.

You may want to read it again.

What this medicine is used for

The name of your medicine is Amcal Prochlorperazine. It contains prochlorperazine maleate.

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.

It 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).

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.

Before you take this medicine

When you must not take it

Do not take if you are under 18 years of age.

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. Always check the ingredients to make sure you can use this medicine.

Symptoms of an allergic reaction to prochlorperazine 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.

You should 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 (EXP) printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take this medicine if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking 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
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you are currently pregnant or you intend to become pregnant.

Like most phenothiazine medicines, prochlorperazine is not recommended for use during pregnancy. If there is a need to take this medicine during your pregnancy, your doctor will discuss with you the benefits and risks of using it.

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

- 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 problems
- constipation
- heart and blood vessel problems, or a family history of these problems such as stroke, blood clots, low blood pressure
- liver disease
- prostate problems
- bowel problems
- epilepsy, seizures or fits
- low blood calcium levels
- thyroid problems like decreased thyroid activity.
- 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

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 any that you buy 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 enzymes such as amitriptyline
- alcohol
- desferrioxamine, a medicine used when you have too much iron in your blood
- procabazine, an anticancer drug
- some medicines used to control epilepsy such as phenobarbital and carbamazepine
- antibiotics used to treat infections
- medicines used to treat high blood pressure and fluid build-up in your body
- medicines to help you sleep
- other medicines used to calm emotional and mental conditions
- medicines used for Parkinson's disease, such as levodopa
- medicines used for the treatment of diabetes
- medicines used to treat high blood pressure or heart problems such as clonidine, guanethidine and propranolol
- medicine used to treat a fast or irregular heartbeat, e.g. amiodarone, quinidine, disopyramide.
- Medicines that can slow your heartbeat 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.
- anticholinergic medicines, includes some medicines used for stomach cramps or spasms, to prevent travel sickness, treat Parkinson's disease or incontinence
- atropine, a medicine which may be used in some eye drops or cough and cold preparations.
- some oral medicines used to prevent your blood from clotting.
- antacids containing magnesium, aluminium and calcium salts, oxides and hydroxides
- adrenaline used for severe allergic reactions
- amphetamine

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 will advise you.

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.

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 glass of water. Do not chew the tablets.

If you take too much (overdose)

Do not try to vomit.

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (13 11 26) or go to the 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

Tell your doctor immediately if you notice any 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.

The condition is 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, which may be due to a serious reaction called Neuroleptic Malignant Syndrome:

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

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

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 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.

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. Exposure to sunlight may cause a skin rash, itching, redness, or even severe sunburn. If your skin does appear to be burning, tell your doctor.

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.

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

If you get any side effects, do not stop taking this medicine without first talking to your doctor or pharmacist.

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

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

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

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 metres above the ground is a good place to store medicines.

Disposal

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

Product description

What it looks like

Amcal Prochlorperazine tablets are white to off-white, circular, uncoated tablets with '5' debossed on one side.

Tablets are available in pack sizes of 5s or 10s.

Ingredients

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

Each tablet also contains the following inactive ingredients:

- 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.

Australian Registration Numbers

Amcal Prochlorperazine:

AUST R 265795.

Sponsor

Apotex Pty Ltd
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