

APO-Prochlorperazine

Contains the active ingredient, prochlorperazine (as 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 this medicine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking 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 need to read it again.

What this medicine is used for

The name of your medicine is APO-Prochlorperazine. It contains the active ingredient, prochlorperazine (as prochlorperazine maleate).

It is used to treat nausea, vomiting and dizziness due to various causes, including migraine (severe headache).

Prochlorperazine belongs to a group of medicines called phenothiazines. It helps to correct chemical 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

Prochlorperazine is not recommended for use in children (under the age of 2 years or children under 10 kg in weight) because children may develop unusual face and body movements.

Do not use Prochlorperazine intramuscular injection in children.

Before you take prochlorperazine

When you must not take it

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

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

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

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty 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 in the past experienced jaundice (yellow skin and/or eyes) or problems with your blood cells, after taking prochlorperazine or similar medicines called phenothiazines.

This is called a hypersensitivity reaction.

Do not take this medicine if you suffer from bone marrow depression, a disease of the blood with a low number of blood cells.

Do not give this medicine to anyone who is in shock, unconscious or in a coma.

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Your doctor will discuss with you the benefits and risks of using it.

Do not breastfeed if you are taking this medicine.

It is recommended that you do not breastfeed while taking prochlorperazine, as it is not known whether it passes into breast milk and there is a possibility that your baby may be affected.

Your doctor will discuss with you the benefits and risks of using it.

Do not take this medicine after the expiry date printed on the pack or

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 start taking this medicine, talk to your doctor.

Before you start to take it

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

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

- phaeochromocytoma, 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 or problems urinating
- constipation or bowel problems
- heart and blood vessel problems, low blood pressure, blood clots,
- liver disease
- prostate problems
- bowel problems
- epilepsy, seizures or fits
- low blood calcium levels associated with a condition called hypoparathyroidism
- hypothyroidism (an underactive thyroid gland)
- 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, or risk factors for diabetes (e.g. overweight)
- you have lost lots of fluid due to vomiting, diarrhoea or sweating (which increases the chance of having low potassium levels)
- a low number of white blood cells (agranulocytosis)
- symptoms of Reye's syndrome in children such as diarrhoea, rapid breathing vomiting and severe fatigue
- chicken pox or measles in children
- dehydration in children.
- experience fever, sore throat or any other infection, they should inform physician and undergo a complete blood count. Treatment should be discontinued if any marked changes (hyperleukocytosis, granulocytopenia) are observed in the blood count.

Tell your doctor if you are planning to have surgery which requires a spinal and/or general anaesthetic.

Make sure to tell your doctor all of your symptoms, in case taking this medicine covers up any undiagnosed problem.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interact with prochlorperazine. 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
- medicines used for the treatment of diabetes

- any other medicines which make you drowsy
- alcohol
- desferrioxamine, used to treat excess iron in your blood
- procarbazine, an anticancer drug
- some medicines used to control epilepsy, e.g. phenytoin, phenobarbital or carbamazepine
- antibiotics used to treat infections
- medicines used to treat Parkinson's disease, e.g. levodopa
- medicines used for the treatment of diabetes
- anticholinergic medicines including those that can be used to relieve stomach cramps, spasms and travel sickness
- 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, e.g. warfarin
- medicines used to treat high blood pressure
- medicines used to treat heart problems, such as clonidine, guanethidine and propranolol
- other medicines which can slow your heart rate down, such as diltiazem, verapamil, beta-blockers (e.g. propranolol), clonidine and guanfacine
- medicines used to treat 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 e.g. diltiazem, verapamil
- diuretic (fluid) tablets, for treating excess fluid and high blood pressure
- 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.
- antacids containing magnesium, aluminium and calcium salts, oxides and hydroxides

- adrenaline used for severe allergic reactions
- amphetamines

These medicines may be affected by prochlorperazine or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect this medicine.

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

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the directions, ask your doctor or pharmacist for help.

How much to take

The usual recommended dose for nausea and vomiting in adults is 1 or 2 tablets two to three times daily.

The usual recommended dose for dizziness in adults is 1 or 2 tablets three to four times daily. This may gradually be reduced to 1 or 2 tablets once a day.

Children are usually given lower doses which depend on their body weight.

If you have liver problems you may take a smaller dose.

How to take it

Swallow the tablets whole with a glass of water.

Do not chew the tablets.

When to take it

Take it at about the same time each day.

Taking your medicine 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 it before, with or after food.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time.

Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

Do not try to vomit.

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much prochlorperazine, you may get some or all of 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 lips and/or 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 people taking phenothiazine medicines, including prochlorperazine.

The condition is more likely to occur during long term treatment with prochlorperazine, especially in elderly women. In very rare cases, this may be permanent.

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.

It may affect other medicines used during surgery.

If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.

If you have diabetes or are at risk of developing diabetes be sure to

monitor your blood glucose levels carefully.

This medicine may affect blood glucose levels.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

Go to your doctor regularly for a check-up.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Things you must not do

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

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

Do not stop taking your medicine or lower the dosage, even if you are feeling better, without checking with your doctor.

Do not stop taking your medicine suddenly. If you do, your condition may worsen or your chance of getting an unwanted side effect may increase. To prevent this, your doctor may gradually reduce the amount of your medicine you take each day before stopping completely.

Do not take any medicines that cause drowsiness while 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 prochlorperazine 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 prochlorperazine makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position. Getting up slowly may help.

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

Your doctor may suggest you avoid alcohol while you are being treated with prochlorperazine.

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. It is advised to avoid exposure to direct sunlight during treatment. 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. For example if you swim in cold water your body may not be able to adjust your body temperature to keep you warm and you may get hypothermia.

Side effects

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

All medicines can have side effects. This medicine helps most people with nausea, vomiting and dizziness, but it may have unwanted side effects in a few people. Sometimes they are serious but most of the time they are not.

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

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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
- ileus paralytic
- drowsiness
- headache
- restlessness, uncontrolled twitching, jerking or writhing movements
- trembling, rigid posture, mask-like face, slow movements and a shuffling unbalanced walk
- blurred vision
- low blood pressure
- change in heart beats
- swelling of the hands, ankles or feet
- skin rash
- for females; unusual secretion of breast milk, irregular or stopping of 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, confusional state, delirium, anxiety
- dizziness
- sedation
- difficulty in breathing
- brownish deposits in the eyes
- stuffy nose

The above list includes the less common side effects of your medicine.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- shortness of breath, wheezing or difficulty in breathing or swallowing
- swelling of the face, lips, throat, tongue or other parts of the body
- cold, clammy skin, palpitations, dizziness, weakness or fainting
- rash, itching or hives on the skin
- unusual muscle tone or spasms causing distortion of the body in children
- General- hypersensitivity, fever, rash, facial swelling, swollen lymph nodes (which could be symptoms relating to raised levels of infection fighting cells (relating to eosinophilia))
- neuroleptic malignant syndrome, a reaction to some medicines with a sudden increase in body temperature, extremely high blood pressure and severe convulsions
- Nervous system related-high fever, muscle cramps or stiffness, dizziness, severe headache, fast heartbeat, confusion, agitation, hallucinations, 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)

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

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

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Product description

What APO-PROCHLORPERAZINE looks like

APO-Prochlorperazine 5 mg tablets

White/off white, round, uncoated tablets marked with "5" on one side. AUST R 158416.

Available in blister packs of 14, 25, 28, 56, 84, 100 and 250 tablets.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

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

It also contains the following:

- lactose monohydrate
- maize starch
- colloidal anhydrous silica
- magnesium stearate

This 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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