

# **APO-PROCHLORPERAZINE**

Contains the active ingredient, prochlorperazine (as maleate)

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## **Consumer Medicine Information**

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

## **What is in this leaflet**

**Read this leaflet carefully before taking your medicine.**

This leaflet answers some common questions about prochlorperazine.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on your medicine may be available. Speak to your pharmacist or doctor to obtain the most up-to-date information.

**Ask your doctor or pharmacist:**

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from [www.apotex.com.au](http://www.apotex.com.au).

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

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 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).

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.

## **How it works**

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.

## **Use in children**

Prochlorperazine is not recommended for use in children (under the age of 2 years or children under 10 kg in weight).

## **Before you take this medicine**

### **When you must not take it**

**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.**
- **You have had an allergic reaction to prochlorperazine, the group of medicines called phenothiazines or any of the ingredients listed at the end of this leaflet.**

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.

- **You must not take prochlorperazine if you suffer from bone marrow depression, a disease of the blood with a low number of blood cells.**
- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

**Prochlorperazine must not be given to anyone who is in shock, unconscious or in a coma.**

## **Before you start to take it**

**Before you start taking this medicine, tell your doctor if:**

**1. You have allergies to:**

- any other medicines
- any other substances, such as foods, preservatives or dyes.

**2. You have or have had any medical conditions, especially the following:**

- 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
- heart and blood vessel problems, low blood pressure, blood clots, stroke (sudden weakness or numbness of the face, arms, or legs, especially on one side, or instances of slurred speech)
- liver disease
- prostate problems
- epilepsy, seizures or fits
- low blood calcium levels associated with a condition called hypoparathyroidism
- hypothyroidism (an underactive thyroid gland)
- narrow-angle 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, muscle stiffness and excessive sweating

- tardive dyskinesia, a reaction to some medicines with uncontrollable twitching or jerking movements of the face, tongue, mouth, jaw, arms and legs
- dementia
- diabetes, or risk factors for diabetes (e.g. overweight)
- QT prolongation (change in the electrical activity of the heart) or conditions which put you at risk of getting QT prolongation (such as slow heartbeat, low potassium levels, family history of QT prolongation) or taking other medicines which prolong the QT interval
- you have lost lots of fluid due to vomiting, diarrhoea or sweating (which increases the chance of having low potassium levels).

**3. You are currently pregnant or you plan to become pregnant.**

Prochlorperazine can affect your baby and is not recommended for use during pregnancy. If there is a need to take prochlorperazine during your pregnancy, your doctor will discuss with you the benefits and risks of using it.

**4. You are currently breastfeeding or you plan to breastfeed.**

It is recommended that you do not breastfeed while taking prochlorperazine, as it is not known whether prochlorperazine passes into breast milk.

If there is a need to take prochlorperazine whilst breastfeeding, your doctor will discuss with you the benefits and risks of using it.

**5. 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.**

Some medicines may interact with prochlorperazine. These include:

- medicines taken to reduce fever
- some medicines used to control depression or mood swings or to calm you down or help you sleep
- 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
- medicines used to treat Parkinson's disease, e.g. levodopa
- 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, or some products available over the counter at pharmacies, 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 digoxin/digitalis, disopyramide, amiodarone and sotalol
- other medicines which can slow your heart rate down, such as diltiazem, verapamil, beta-blockers (e.g. propranolol), clonidine and guanfacine
- diuretic (fluid) tablets, for treating excess fluid and high blood pressure
- tetracosactide, used for diagnosing some illnesses
- cisapride, used for treating some stomach problems
- halofantrine, used for treating malaria
- certain medicines for treating infections: erythromycin or amphotericin B (when given via injection or infusion); pentamidine and sparfloxacin
- thioridazine, sultopride and other antipsychotics
- stimulant laxatives containing, for example, bisacodyl or senna

- methadone, a strong painkiller
- some anti-inflammatory drugs such as steroid medicines (glucocorticoids)
- other medications such as vincamine i.v. injection.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with prochlorperazine.

## **How to take this medicine**

Follow all directions given to you by your doctor carefully. Their instructions may be different to the information in this leaflet.

## **How much to take**

Your doctor will tell you how many you will need to take. This depends on your condition and whether or not you are taking any other medicines.

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.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

## **How to take it**

Swallow APO-Prochlorperazine 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. Tell your doctor that you are taking this medicine if:

- You become pregnant
- You are about to have any blood tests

**You are planning to have surgery and you are taking this medicine. 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.

**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.

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

## **Things you must not do**

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without checking with your doctor.

## **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, 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 prochlorperazine 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. 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.

## **Possible side effects**

Tell your doctor as soon as possible if you do not feel well while you are taking prochlorperazine.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

### **Tell your doctor if you notice any of the following:**

- constipation, dry mouth
- drowsiness
- headache
- restlessness, twitching
- trembling, rigid posture, mask-like face, slow movements and a shuffling unbalanced walk
- blurred vision

**Tell your doctor as soon as possible if you notice any of the following.**

These may be serious side effects and you may need medical attention.

- tardive dyskinesia, a reaction to some medicines with uncontrollable twitching or jerking movements of the face, tongue, mouth, jaw, arms and legs
- low blood pressure
- swelling of the hands, ankles or feet
- dermatitis, skin rash, hives, sunburn after only a small time in the sun, flaking skin, red, itchy spots, unusual skin pigmentation
- sudden uncoordinated movements
- signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- feeling tired due to lowered levels of blood cells
- night blindness, worsening sight
- unusual secretion of breast milk
- breast enlargement
- for females: changes in periods
- for males: problems ejaculating
- severe pain in the stomach with bloating, cramps and vomiting

- difficulty passing urine
- yellowing of the skin and/or eyes (jaundice)
- insomnia
- high or low blood sugar levels
- confusion, excitement or agitation
- trance-like state
- raised body temperature

**If any of the following happen, do not take any more of your medicine and either tell your doctor immediately or go to Accident and Emergency department at your nearest hospital:**

- unusual muscle tone or spasms causing distortion of the body in children
- neuroleptic malignant syndrome, a reaction to some medicines with a sudden increase in body temperature, extremely high blood pressure and severe convulsions
- blood clots - for example, red, painful swollen areas in the leg; or clots in the lung seen by sudden breathlessness, coughing up blood cough or pain when breathing
- other problems breathing, blue lips and/or skin
- changes in heart rate or rhythm

- seizures
- coma

## **Allergic reactions**

**If you think you are having an allergic reaction to prochlorperazine do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

## **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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

## **Product description**

### **What APO-PROCHLORPERAZINE looks like**

#### **APO-Prochlorperazine 5 mg tablets:**

White, round and marked with "5".

Available in blister packs of 25 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 inactive ingredients:

- Lactose
- Maize starch
- Colloidal anhydrous silica
- Magnesium stearate

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

## **Australian Registration Numbers**

**APO-Prochlorperazine 5 mg tablets (blisters):**

AUST R 158416

## **Sponsor**

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113

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