

CHEMISTS' OWN PROCALM

prochlorperazine maleate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CHEMISTS' OWN PROCALM. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking CHEMISTS' OWN PROCALM against the benefits they expect it will have for you.

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

Keep this leaflet with your medicine. You may need to read it again.

What CHEMISTS' OWN PROCALM is used for

CHEMISTS' OWN PROCALM 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.

CHEMISTS' OWN PROCALM is used to treat nausea, vomiting and dizziness due to various causes, including migraine (severe headache).

Your doctor may have prescribed this medicine for another reason.

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

CHEMISTS' OWN PROCALM is available in packs of 10 tablets from your pharmacist. Ask your doctor or pharmacist if you have any questions why CHEMISTS' OWN PROCALM has been recommended for you.

Before you take it

When you must not take it

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

Do not take CHEMISTS' OWN PROCALM if you have an allergy to:

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

Symptoms of an allergic reaction to CHEMISTS' OWN PROCALM 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 CHEMISTS' OWN PROCALM 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.

CHEMISTS' OWN PROCALM must not be given to anyone who is unconscious or in a coma.

Do not take any medicines that cause drowsiness while you are taking CHEMISTS' OWN PROCALM.

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 it if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking CHEMISTS' OWN PROCALM, 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 pregnant or intend to become pregnant.

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

Tell your doctor or pharmacist if you are breastfeeding or plan to breastfeed.

It is recommended that you do **not** breastfeed while taking CHEMISTS' OWN PROCALM, as it is not known whether this medicine passes into breast milk.

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
- heart and blood vessel problems, low blood pressure
- blood clots
- liver disease
- prostate problems
- bowel problems
- epilepsy, seizures or fits
- low blood calcium levels
- 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
- 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.

Use in children

Do not use in children less than 1 year.

Tell your doctor if you are about to have any surgery which requires a general anaesthetic.

If you have not told your doctor or pharmacist about any of the

above, tell them before you start taking CHEMISTS' OWN PROCALM.

Taking other medicines

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

Some medicines may be affected by CHEMISTS' OWN PROCALM, or may affect how well it works. These include:

- some medicines used to control depression, mood swings, or mental illness such as lithium
- medicines metabolised by CYP2D6 enzymes such as amitriptyline
- alcohol
- desferrioxamine, a drug used in iron overdose
- procarbazine, an anticancer drug
- some medicines used to control epilepsy such as phenobarbital and carbamazepine
- antibiotics used to treat infections
- medicines used to treat Parkinson's disease such as levodopa
- medicines used for the treatment of diabetes
- anticholinergic medicines which are 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
- medicines used to treat fluid build-up in your body
- medicine used to treat high blood pressure or heart problems such as clonidine, guanethidine and propranolol.
- Medicine 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 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
- antacids containing magnesium, aluminium and calcium salts, oxides and hydroxides
- adrenaline used for severe allergic reactions
- amphetamine.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking CHEMISTS' OWN PROCALM.

How to take it

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

They may differ from the information contained in this leaflet.

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

How much to take

Adults 18 years of age and older:

For the treatment of nausea associated with migraine, take 1 or 2 tablets two or three times a day if necessary or as advised by your pharmacist. If symptoms persist, see your doctor.

Do not use in children and adolescents under 18 years of age.

How to take it

Swallow CHEMISTS' OWN PROCALM tablets whole with a glass of water. Do not chew the tablets.

When to take it

It does not matter if you take CHEMISTS' OWN PROCALM before or after food.

If you are not sure what to do, ask your doctor or pharmacist.

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

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 Accident and Emergency at your nearest hospital if you think that you, or anyone else, has taken too much CHEMISTS' OWN PROCALM. 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.

Your doctor or pharmacist has information on how to recognize and treat an overdose.

Ask your doctor or pharmacist if you have any concerns.

While you are taking it

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 medicine, including CHEMISTS' OWN PROCALM.

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

Tell any other doctors, dentists and pharmacists who are treating you that you are taking CHEMISTS' OWN PROCALM.

If you are about to be started on any new medicines, tell your doctor, dentist or pharmacist that you are taking CHEMISTS' OWN PROCALM.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking CHEMISTS' OWN PROCALM.

If you become pregnant while taking CHEMISTS' OWN PROCALM, tell your doctor immediately.

Things you must not do

Do not give CHEMISTS' OWN PROCALM to anyone else, even if they have the same condition as you.

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

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

If you stop taking CHEMISTS' OWN PROCALM suddenly, your

condition may worsen or your chance of getting an unwanted side effect may increase. To prevent this, your doctor or pharmacist may gradually reduce the amount of CHEMISTS' OWN PROCALM you take each day before stopping completely.

Do not take any medicines that causes drowsiness while you are taking CHEMISTS' OWN PROCALM.

Things to be careful of

Be careful driving or operating machinery until you know how CHEMISTS' OWN PROCALM affects you.

As with other medicines, CHEMISTS' OWN PROCALM may cause dizziness, light-headedness, blurred vision, tiredness, drowsiness in some people.

Make sure you know how you react to CHEMISTS' OWN PROCALM before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive.

If you drink alcohol, dizziness, drowsiness or light-headedness may be worse.

If CHEMISTS' OWN PROCALM 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 CHEMISTS' OWN PROCALM. Combining it with alcohol can make you more sleepy, dizzy or light-headed.

Your doctor may suggest you avoid alcohol while you are being treated with CHEMISTS' OWN PROCALM.

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

CHEMISTS' OWN PROCALM 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.

CHEMISTS' OWN PROCALM 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 CHEMISTS' OWN PROCALM.

This medicine helps most people with nausea, vomiting and dizziness, 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 CHEMISTS' OWN PROCALM 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
- low blood pressure

The following side effects are less common:

- changes in heart beats
- swelling of the hands, ankles or feet
- skin rash
- for females: unusual secretion of breast milk, irregular or stopping 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.

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

Allergic reaction related (that can occur either immediately or within several days of drug administration that may be life threatening):

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

These are very serious side effects. You may need urgent medical attention or hospitalisation.

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 side effects.

You may not experience any of them.

After using it

Storage

Keep CHEMISTS' OWN PROCALM tablets in a cool dry place where the temperature stays below 25°C. Protect from light.

Keep your CHEMISTS' OWN PROCALM in the pack until it is time to take them.

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

Do not store CHEMISTS' OWN PROCALM or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot days or on window sills.

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 or pharmacist tells you to stop taking CHEMISTS' OWN PROCALM, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Australian registration numbers:
CHEMISTS' OWN PROCALM -
AUST R 183037

Date of preparation: Jan 2024.

Product description

What it looks like

CHEMISTS' OWN PROCALM is a white to off-white circular, uncoated tablets with "5" debossed on one side.

Each pack contains 10 tablets.

Ingredients

The active ingredient in CHEMISTS' OWN PROCALM is prochlorperazine maleate

Each CHEMISTS' OWN PROCALM tablet contains 5 mg of prochlorperazine maleate.

The tablets also contain:

- lactose monohydrate
- maize starch
- colloidal anhydrous silica
- magnesium stearate
- purified water.

This medicine contains sugars as lactose.

Supplier

Arrotex Pharmaceutical Pty Ltd
15 – 17 Chapel Street
Cremorne VIC 3121
Australia
www.arrotex.com.au