CHEMISTS' OWN PROCALM

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Chemists' Own Procalm?

Chemists' Own Procalm contains the active ingredient prochlorperazine maleate. Chemists' Own Procalm is used to treat nausea associated with migraine (severe headache). For more information, see Section 1. Why am I using Chemists' Own Procalm? in the full CMI.

2. What should I know before I use Chemists' Own Procalm?

Do not use if you have ever had an allergic reaction to prochlorperazine maleate or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section 2. What should I know before I use Chemists' Own Procalm? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Chemists' Own Procalm and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Chemists' Own Procalm?

- Your doctor or pharmacist will tell you how much Chemists' Own Procalm you will need to take each day.
- The usual recommended dose for nausea associated with migraine is 1 or 2 tablets two to three times a day.

More instructions can be found in Section 4. How do I use Chemists' Own Procalm? in the full CMI.

5. What should I know while using Chemists' Own Procalm?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Chemists' Own Procalm. • Tell your doctor 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. • If outdoors, wear protective clothing and use at least a SPF 15+ sunscreen.
Things you should not do	• Do not give Chemists' Own Procalm to children and adolescents under 18 years of age.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how Chemists' Own Procalm affects you. • It may cause dizziness, light-headedness, tiredness and drowsiness in some people.
Drinking alcohol	• Be careful when drinking alcohol while taking Chemists' Own Procalm. • If you drink alcohol, dizziness or lightheadedness may be worse.
Looking after your medicine	• Keep Chemists' Own Procalm in a cool, dry place. Protect from light. • Keep Chemists' Own Procalm where young children cannot reach it.

For more information, see Section 5. What should I know while using Chemists' Own Procalm? in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Chemists' Own Procalm. Some common side effects include constipation, dry mouth, drowsiness, trembling, rigid posture, twitching and blurry vision.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI

CHEMISTS' OWN PROCALM

Active ingredient(s): *prochlorperazine maleate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Chemists' Own Procalm. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Chemists' Own Procalm.**

Where to find information in this leaflet:

1. Why am I using Chemists' Own Procalm?
2. What should I know before I use Chemists' Own Procalm?
3. What if I am taking other medicines?
4. How do I use Chemists' Own Procalm?
5. What should I know while using Chemists' Own Procalm?
6. Are there any side effects?
7. Product details

1. Why am I using Chemists' Own Procalm?

Chemists' Own Procalm contains the active ingredient prochlorperazine maleate. Chemists' Own Procalm belongs to a group of medicines called phenothiazines.

It helps to correct chemical imbalances in the brain, allowing function correctly.

These chemicals may also affect the parts of the brain which control nausea (feeling sick).

Chemists' Own Procalm is used to treat nausea associated with migraine (severe headache).

There is no evidence that it is addictive.

2. What should I know before I use Chemists' Own Procalm?

Warnings

Do not use Chemists' Own Procalm if:

- you are taking other medicines that cause drowsiness
- you are allergic 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 asthma, wheezing, shortness of breath, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, skin rash, itching or hives.
- Always check the ingredients to make sure you can use this medicine.
- You have any of the following medical conditions:
  - shock
  - disease of the blood with a low number of blood cells
  - beign unconscious or in coma (especially from alcohol or medications).

Check with your doctor if you:

- you have allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
- have any other medical conditions, especially the following:
  - phaechromocytoma, 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
  - an underactive thyroid gland
  - glaucoma, a condition in which there is usually 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 (especially in elderly)
  - diabetes
  - agranulocytosis, which affects blood ccount
  - schizophrenia, a mental illness
- have a migraine (severe headache) before you first use Chemists' Own Procalm.
- take any medicine used to control depression, mood swings or mental illness such as monoamine oxidase inhibitors (MAOIs). MAOIs should be stopped at least 14 days before you start taking Chemists' Own Procalm.
- take any medicines for any other condition.

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. See additional information under Section 6. Are there any side effects?

Use in children

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

Pregnancy and breastfeeding

Use of Chemists' Own Procalm is not recommended during pregnancy.

Check with your doctor if you are a woman of childbearing age and not using effective contraception, or if you are pregnant, might become pregnant or think you may be pregnant. 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.

Use of Chemists' Own Procalm is not recommended during breastfeeding. If you are breastfeeding or planning to breastfeed, talk to your doctor about using Chemists' Own Procalm.

It is not recommended to take Chemists' Own Procalm while breastfeeding as it is not known whether Chemists' Own Procalm passes into breast milk.

Use in Elderly

Chemists Own Procalm should be used with caution in the elderly particularly during very hot or very cold weather. The elderly are more likely to experiencing dizziness and drowsiness.

3. What if I am taking other medicines?

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

Some medicines may interfere with Chemists' Own Procalm and affect how it works. These include:

- some medicines used to control depression or mood swings or mental illness such as lithium
- sedative medicines (medicine used to help you sleep)
- general anaesthetics
- opiates or other analgesics (pain relief medicine
- alcohol
- desferrioxamine, a drug used in iron overdose
- certain anticancer medicines such as procarbazine
- 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
- 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 high blood pressure or heart problems such as clonidine, guanethidine and propranolol
- 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 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.
- antacids containing magnesium, aluminium and calcium salts, oxides and hydroxides
- adrenaline, bepridil, cisapride, sultopride, thioridazine, methadone, erythromycin injection, vincamine injection, halofantrine, pentamidine, sparfloxacin, amphotericin B injection, glucocorticoids, tetracosactides (tetracosactrin)
- amfetamine, a stimulant drug

These medicines may be affected by Chemists' Own Procalm 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Chemists' Own Procalm.

4. How do I use Chemists' Own Procalm?

How much to use

Your doctor or pharmacist will tell you how much Chemists' Own Procalm you will need to take each day. This depends on your condition and whether or not you are taking any other medicines**.**

Adults 18 years of age and older:

- The usual recommended dose for nausea associated with migraine is 1 or 2 tablets two to three times 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.

When to use Chemists' Own Procalm

- It does not matter if you take Chemists' Own Procalm before or after food.

How to use Chemists' Own Procalm:

- Swallow Chemists' Own Procalm tablets whole with a full glass of water.
- Do not chew the tablets.

If you use too much Chemists' Own Procalm

If you think that you have used too much Chemists' Own Procalm, you may need urgent medical attention.

Do not try to vomit.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or

- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Symptoms of overdose may include tiredness, coma, restlessness, shaking, muscle twitching, muscle weakness, spasm, confusion, excitement or agitation, low blood pressure, fast heartbeat, decrease body temperature, small pupils in the eye, difficulty in swallowing or breathing or blue skin, difficulty speaking, or convulsions.

Your doctor or pharmacist has information on how to recognise and treat an overdose. Ask your doctor or pharmacist if you have any concerns.

5. What should I know while using Chemists' Own Procalm?

Things you should do

- If outdoors, wear protective clothing and use at least a SPF 15+ sunscreen. Chemists' Own Procalm 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 severe sunburn.
- 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.
- If Chemists' Own Procalm makes you feel light-headed, dizzy or faint, get up slowly from a sitting or lying position.
- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Chemists' Own Procalm.
- 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.

Call your doctor straight away 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 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.
- become pregnant while taking Chemists' Own Procalm.

Things you should not do

- Do not give Chemists' Own Procalm to anyone else, even if they have the same condition as you.
- Do not take Chemists' Own Procalm 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.
- Do not stop taking Chemists' Own Procalm 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 Chemists' Own Procalm you take each day before stopping completely.
- Do not take any medicines that cause drowsiness while you are taking Chemists' Own Procalm.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Chemists' Own Procalm affects you.

Chemists' Own Procalm may cause dizziness, light-headedness, tiredness and drowsiness in some people. If this occurs do not drive.

Drinking alcohol

Tell your doctor if you drink alcohol.

Be careful when drinking alcohol while taking Chemists' Own Procalm**.** If you drink alcohol, dizziness, drowsiness or light- headedness may be worse.
Your doctor may suggest you avoid alcohol while you are being treated with Chemists' Own Procalm.

Looking after your medicine

- 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 well.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills. Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects.

If you do experience any side effects, do not stop taking Chemists' Own Procalm without first talking to your doctor or pharmacist. Most side effects are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• constipation • dry mouth • drowsiness • restlessness • trembling, rigid posture, mask-like face, slow movements and a shuffling unbalanced walk • twitching • blurred vision • agitation, confusion, delirium, anxiety • skin sensitization.	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• dizziness, light-headedness • changes in heart beat • swelling of the hands, ankles or feet • swelling and redness along a vein which is extremely tender when touched, which may be a serious blood clot • for females: unusual secretion of breast milk, irregular periods • for males: breast enlargement, difficulty in ejaculating • severe pain in the stomach with bloating, gut cramps and vomiting • difficulty passing urine • yellowing of the skin and/or eyes • headache • insomnia • difficulty in breathing • frequent infections such as fever, severe chills, sore throat or mouth ulcers • bleeding or bruising more easily than normal • nasal stuffiness • excessive thirst • dry mouth and skin • eye problems such as changes in vision, changes in eye colour, uncontrolled eye movements or eye pain.	**Call your doctor straight immediately, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**
• Unusual muscle tone or • unusual muscle tone or spasms causing distortion of the body in children • chest pain and shortness of breath • seizures or convulsions.	**If any of the following happen, go to Accident and Emergency at your nearest hospital.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What Chemists' Own Procalm tablets contains

Active ingredient (main ingredient)	prochlorperazine maleate 5 mg
Other ingredients (inactive ingredients)	lactose monohydrate maize starch colloidal anhydrous silica magnesium stearate purified water

This medicine contains sugars as lactose.

Do not take this medicine if you are allergic to any of these ingredients.

What Chemists' Own Procalm looks like

Chemists' Own Procalm tablet is a white to off-white circular, uncoated tablets marked with "5" debossed on one side.

Each pack contains 10 tablets (AUST R 183037)

Who distributes Chemists' Own Procalm

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121
Australia

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