

PLEASE READ THIS INFORMATION CAREFULLY BEFORE YOU START TO TAKE YOUR MEDICINE. CONSUMER MEDICINE INFORMATION (CMI)



Pharmacy Health™

PROMETHAZINE

PROMETHAZINE HYDROCHLORIDE

What is in this leaflet

This leaflet answers some common questions about Pharmacy Health Promethazine. It does not contain all the available information. It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits. Your pharmacist or doctor has weighed the risks of you taking Pharmacy Health Promethazine against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Pharmacy Health Promethazine is used for

Pharmacy Health Promethazine is an antihistamine used for:

- Relief of allergies including hay fever, allergic or itchy skin conditions such as allergic contact dermatitis or hives, allergic reaction to bites and stings
- relief of runny nose due to hay fever or allergic rhinitis
- short-term use for sedation on the advice of a pharmacist or doctor
- assists in the management of the symptoms of chicken pox and measles by acting as a sedative.
- prevention and treatment of travel sickness
- treatment of nausea and vomiting

Antihistamines help reduce allergic symptoms by preventing the effects of a substance called histamine. Histamine is produced by the body in response to foreign substances that the body is allergic to. Your pharmacist or doctor may have recommended Pharmacy Health Promethazine for another reason.

Ask your pharmacist or doctor if you have any questions about this medicine.

Before you take it

When you must not take it

Do not take Pharmacy Health Promethazine if you have an allergy to:

- any medicine containing promethazine hydrochloride
- any of the ingredients listed at the end of this leaflet

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 Pharmacy Health Promethazine:

- if you are also taking monoamine oxidase inhibitors, a type of medicine used to treat depression
- if you have jaundice.
- if you are receiving or have received high doses of other CNS depressant medications (for example, drugs that are used to treat anxiety and sleep disorders).

Any person who is unconscious or in a coma must not be treated with Pharmacy Health Promethazine.

Do not give Pharmacy Health Promethazine to:

- newborn or premature babies.
- children under six years of age, due to the potential for fatal respiratory depression.

Do not use Pharmacy Health Promethazine:

- if you are breastfeeding or plan to breastfeed. It passes into the breast milk and there is a possibility that the baby may be affected.
- 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.
- if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your pharmacist or doctor if you have allergies to:

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

Tell your pharmacist or doctor if you have or have had any medical

conditions,

especially the following:

- **kidney or liver disease**
- **epilepsy**
- **cardiovascular disease**
- **blood pressure problems**
- **bladder problems**
- **breathing problems**
- **glaucoma - an eye condition**
- **prostate problems**
- **stomach ulcer or blockage**

Tell your doctor if you plan to have surgery.

Tell your pharmacist or doctor if you take sedatives.

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

Promethazine is not recommended for use during pregnancy. If there is a need to consider Pharmacy Health Promethazine during your pregnancy, your pharmacist or doctor will discuss with you the benefits and risks of taking it.

Taking other medicines

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

Some medicines and Pharmacy Health Promethazine may interfere with each other. Pharmacy Health Promethazine may increase the sedative effect of some drugs. These include:

- medicines used to treat depression, especially monoamine oxidase inhibitors and tricyclic antidepressants
- medicines used to help you sleep or relax (sedatives and hypnotics)
- opioid analgesics, medicines used to treat pain
- other antihistamines
- alcohol

These medicines may be affected by Pharmacy Health Promethazine or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

How to take it

How much to take

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

They may differ from the information contained in this leaflet.

Pharmacy Health Promethazine are recommended for adults and children over 6 years of age. Pharmacy Health Promethazine tablets should not be given to children aged between 6 and 11 years, except on the advice of your pharmacist or doctor.

Allergies

Adults and children over 12 years of age:

Promethazine 10 (10 mg): 1 – 2 tablets, 2 – 3 times a day

Promethazine 25 (25 mg): 1 – 3 tablets at night

Children 6 – 12 years:

Promethazine 10 (10 mg): 1 tablet, 2 – 3 times a day / 1 – 2 tablets at night

Promethazine 25 (25 mg): 1 tablet at night

Sedation

For short term use on the advice of a pharmacist or doctor. Do not use for more than 7 to 10 consecutive days.

Adults and children over 12 years of age:

Promethazine 25 (25 mg): 1 – 3 tablets at night

Children 6 – 12 years:

Promethazine 10 (10 mg): 1 – 2 tablets at night

Promethazine 25 (25 mg): 1 tablet at night

Prevention of Travel Sickness

Adults and children over 12 years of age:

Promethazine 10 (10 mg): 1 – 2 tablets the night before travel

Promethazine 25 (25 mg): 1 tablet the night before travel

Children 6 – 12 years:

Promethazine 10 (10 mg):1 tablet the night before travel

Treatment of Travel Sickness

Adults and children over 12 years of age:

Promethazine 10 (10 mg): 1 – 2 tablets as a single daily dose

Promethazine 25 (25 mg): 1 tablet daily as a single daily dose

Children 6 – 12 years:

Promethazine 10 (10 mg): 1 tablet daily as a single daily dose

Nausea and Vomiting

Adults and children over 12 years of age:

Promethazine 10 (10 mg): 2 tablets, 3 times a day

Promethazine 25 (25 mg): 1 tablet, 3 – 4 times a day

Children 6 – 12 years:

Promethazine 10 (10 mg): 1 tablet, 2 times a day

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

Do not take more than the recommended dose.

Use this drug only as recommended. Do not exceed the recommended dose. There have been case reports of promethazine abuse.

Use in the Elderly

If you are over 65 years of age, talk to your pharmacist or doctor about how much to take. Elderly patients are more likely to have side effects from taking these medicines.

How to take it

Swallow tablets whole with a full glass of water.

How long to take it

Pharmacy Health Promethazine should not usually be taken for more than 10 days in a row. If your symptoms persist, see your pharmacist or doctor for advice.

If you forget to take it

If you are taking Pharmacy Health Promethazine for an allergic disorder and you forget to take your bedtime dose, you may need to take your dose in two or three smaller doses during the following day.

Check with your pharmacist or doctor.

If you are taking Pharmacy Health Promethazine for travel sickness or nausea and vomiting, take your dose as soon as you remember.

If you are taking Pharmacy Health Promethazine for sedation, take your dose as soon as you remember.

Be careful because you may still be affected in the morning. **Do not take a double dose to make up for the dose that you missed.** This may be harmful.

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

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre on 13 11 26 (Australia) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Pharmacy Health Promethazine.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Pharmacy Health Promethazine, you may experience:

Adults:

- drowsiness
- convulsions and/or tremors
- difficulty breathing
- unconsciousness
- acute anxiety
- hallucinations

Children:

- over - excitement
- shaky and unsteady movements
- convulsions and/or tremors
- hallucinations
- difficulty breathing
- unconsciousness
- high fever

While you are taking it

Things you must do

If you have eczema or a tendency to rheumatism, Pharmacy Health Promethazine may cause your skin to be more sensitive to the sun. You should protect your skin from exposure to bright sunlight.

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Pharmacy Health Promethazine.

If you are about to be started on any new medicine, tell your pharmacist or doctor that you are taking Pharmacy Health Promethazine.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.

If you become pregnant while you are taking this medicine, stop taking it and tell your doctor immediately.

Talk to your pharmacist or doctor if your symptoms do not improve.

Your pharmacist or doctor will assess your condition and decide if you should continue to take the medicine.

Things you must not do

Do not give Pharmacy Health Promethazine to anyone else, even if they have the same condition as you.

Do not take Pharmacy Health Promethazine to treat any other complaints unless your pharmacist or doctor tells you to.

Do not drink alcohol while taking Pharmacy Health Promethazine.

The sedation effects of alcohol may be increased.

Do not take more than the recommended dose unless your pharmacist or doctor tells you to.

Things to be careful of

Promethazine is a known sedative and may cause drowsiness in some people.

Make sure you know how you react to Pharmacy Health Promethazine before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy. If this occurs do not drive or operate machinery.

If you have a single dose at bedtime, you may still be affected in the morning. A very serious health problem called neuroleptic malignant syndrome (NMS) may happen. Stop treatment and call your doctor right away if you have high fever, muscle cramps or stiffness, dizziness, very bad headache, fast heartbeat, confusion, agitation, hallucinations, or are sweating a lot.

Avoid alcohol.

Children and the elderly are especially sensitive to the effects of antihistamines.

Side effects

Promethazine may have unwanted side effects in some 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.

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking Pharmacy Health Promethazine.

Tell your pharmacist or doctor if you notice any of the following and they worry you:

- dry mouth, nose & throat
- stomach upset
- loss of appetite
- nausea or vomiting
- diarrhoea or constipation
- tiredness or sleepiness
- restlessness
- blurred vision
- dizziness

The above list includes the more common side effects of Pharmacy Health Promethazine. They are usually mild.

Tell your pharmacist or doctor immediately if you notice any of the following:

- fever
- difficulty breathing
- irregular heart beat
- jaundice - yellow tinge to skin or eyes
- tremors or convulsions
- tinnitus - buzzing, hissing, ringing or other persistent noise in the ears
- seizures (fits)
- hallucinations
- neuroleptic malignant syndrome (NMS)
 - See "Things to be careful of" for more information.
 - severe uncontrollable muscular movements

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

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

- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin rashes

The above list includes symptoms of an allergic reaction. You may need urgent medical attention or hospitalisation. Allergic reactions are rare.

Tell your pharmacist or doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some patients.

Do not be alarmed by the lists of possible side effects.

You may not experience any of them.

Ask your pharmacist or doctor if you have any questions.

After taking Pharmacy Health Promethazine

Storage

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

If you take your medicine out of the pack it will not keep as well.

Keep your tablets in a cool dry place where the temperature stays below 25°C. Do not store Pharmacy Health Promethazine 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 pharmacist or doctor tells you to stop taking Pharmacy Health Promethazine or if it has passed the expiry date, ask your pharmacist what to do with any left over.

What it looks like

Pharmacy Health Promethazine are available in two strengths:

Pharmacy Health Promethazine 10 are blue-coloured, round, biconvex, film-coated tablets, plain on both sides.

Pharmacy Health Promethazine 25 are blue-coloured, round, biconvex, film-coated tablets, plain on both sides.

Both tablet strengths are available in blister packs of 50 tablets.

Ingredients

Active ingredient:

Pharmacy Health Promethazine 10 contains 10 mg of promethazine hydrochloride per tablet. Pharmacy Health Promethazine 25 contains 25 mg of promethazine hydrochloride per tablet.

Inactive ingredients:

- Hypromellose
- Indigo carmine aluminium lake
- Lactose monohydrate
- Polyethylene glycol/macrogol
- Magnesium stearate
- Maize starch
- Povidone
- Titanium dioxide

Supplier

Pharmacy Health Promethazine is supplied in Australia by: Pharmacy Health
11 Grand Avenue,
Camelia NSW 2142, Australia.

This leaflet was prepared October 2018

10 mg AUST R 317346

25 mg AUST R 317345

EPH317345v1