Phenergan® (fen-er-gan)

Active ingredient: *Promethazine hydrochloride* (PRO-meth-ar-zine HIGH-dro (h)-CLOR-ride)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Phenergan. **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 Phenergan.**

Where to find information in this leaflet:

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

1. Why am I using Phenergan?

Phenergan contains the active ingredient promethazine hydrochloride.

Phenergan is an antihistamine used to treat a number of conditions:

- **allergies - allergic contact dermatitis, hives, hayfever, bites and stings**
- **respiratory symptoms due to allergies - runny nose**
- **nausea and vomiting - motion sickness**
- **assists in the management of the symptoms of chicken pox and measles by acting as a sedative**
- **for short-term use for sedation on the advice of a pharmacist or doctor - do not use for more than 7-10 days**

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 Phenergan for another reason.

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

2. What should I know before I use Phenergan?

Warnings

Phenergan must not be used in children under 6 years of age, due to the potential for fatal respiratory depression, psychiatric and CNS events.

Do not use Phenergan if:

- you are allergic to promethazine hydrochloride, medicines of similar properties or belonging to the specific family of chemicals called phenothiazines, other phenothiazines, or any of the ingredients listed at the end of this leaflet.

  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

  If you take this medicine after the expiry date has passed, it may not work as well.

- **the packaging is torn or shows signs of tampering.**

Any person who is unconscious or in a coma must not be treated with Phenergan.

Do not give Phenergan to newborn or premature babies.

Check with your doctor or pharmacist if you:

- have allergies to:
  - any other medicines
  - any other substances, such as foods, preservatives or dyes
- have or have had any medical conditions, especially the following:
  - kidney or liver disease
  - Parkinson's disease
  - underactive thyroid gland (hypothyroidism)
  - tumour growing in adrenal glands (pheochromocytoma)
  - autoimmune disorder (myasthenia gravis)
  - epilepsy
  - cardiovascular disease/cardiac failure
  - blood pressure problems
  - low blood cell count (agranulocytosis)
  - bladder problems
  - breathing problems
  - glaucoma - an eye condition
  - prostate problems
  - stomach ulcer or blockage
- develop a fever or an infection to confirm if laboratory tests are required to check your blood count.
- plan to have surgery
- take sedatives
- take any medicines for any other condition
- have any personal or family history of heart disease
- have an irregular heartbeat

If you experience an allergic reaction, seek medical help right away.

Caution must be exercised when using Phenergan due to the risk of sedation.

If you experience fever, sore throat or any other infection, you should inform your doctor or pharmacist immediately and undergo a complete blood count. Treatment should be discontinued if any marked changes are observed in the blood count.

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?

Pregnancy and breastfeeding

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

Do not take Phenergan if you are pregnant or plan to become pregnant.

It may affect your developing baby if you take it during pregnancy. If there is a need to consider Phenergan during your pregnancy, Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

Do not take Phenergan 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.

Use in Children

- **Do not give Phenergan to newborn or premature babies.**
- **Phenergan must not be used in children under 6 years of age, due to the potential for fatal respiratory depression , psychiatric and CNS events.**
- **Because of the risk of chocking, the tablets should be avoided in children who have difficulty swallowing tablets.**

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 Phenergan and affect how it works

Phenergan may increase the sedative effect of some medicines. 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 and alcohol containing medicines
- medicines for the treatment of irregular heartbeats (antiarrhythmics)
- medicines that help with your mood (antidepressants)
- medicines used to help with mental illness (antipsychotics)
- medicines to treat infections (antimicrobials)
- medicines used to treat nausea and vomiting like metoclopramide
- medicines used to relieve muscle spasm like carisoprodol and cyclobenzaprine
- medicines for the treatment of epilepsy or seizures
- medicines used to treat acid indigestion such as magnesium, aluminium and calcium salts, oxides and hydroxides
- medicines used to smooth muscle contractions in the gastrointestinal tract (antispasmodics)

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

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

4. How do I use Phenergan?

How much to take

- Follow the instructions provided with the medicine.

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

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

  They may differ from the information contained in this leaflet.

- Use this drug only as recommended.
- Do not exceed the recommended dosage. There have been case reports of promethazine abuse.
- Phenergan tablets and elixir are recommended for adults and children over 6 years of age.
- **It is recommended that the lowest effective dose of Phenergan be used in children 6 years of age or older.**

Allergic Disorder

- Adults: One to three 25mg tablets as a single dose at night, or one to two 10mg tablets, two to three times daily.
- Children 6-12 years: One to two 10mg tablets, or 10 to 25mL of the elixir as a single dose at night, or one 10mg tablet, or 10mL of the elixir, two to three times daily.

Sedation

- For short term use on the advice of a pharmacist or doctor.

- Adults: One to three 25mg tablets as a single dose at night.
- Children 6-12 years: One to two 10mg tablets, or 10 to 25mL of the elixir, as a single dose at night.

Travel Sickness

- Adults: One 25mg tablet.
- Children 6-12 years: One 10mg tablet or 10mL of the elixir.
- To be taken the night before travel and repeated after 6 to 8 hours on the following day if required.

Nausea and Vomiting

- Adults: One 25mg tablet every 4 to 6 hours to a maximum daily dose of four 25mg tablets.
- Children 6-12 years: One 10mg tablet or 10mL of the elixir, every 4 to 6 hours to a maximum daily dose of two 10mg tablets or 25mL of the elixir.

Use in the Elderly

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

How to take Phenergan

Tablets

- Swallow Phenergan tablets whole with a full glass of water.

Elixir

- Measure out the amount of elixir to be taken.

How long to take it

Phenergan 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 Phenergan 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 Phenergan for travel sickness or nausea and vomiting, take your dose as soon as you remember.

If you are taking Phenergan 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 use too much Phenergan (overdose)

If you think that you have used too much Phenergan, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26 in Australia or 0800 764 766 in New Zealand**), 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.

If you take too much Phenergan, you may experience:

Adults

- drowsiness
- convulsions and/or tremors
- difficulty breathing
- unconsciousness
- acute anxiety
- hallucinations
- heart palpitations, chest pain and/or rapid pulse
- dizziness
- nausea
- cold sweats

Children

- over - excitement
- shaky and unsteady movements
- convulsions and/or tremors
- hallucinations
- difficulty breathing
- unconsciousness
- high fever
- heart palpitations, chest pain and/or rapid pulse
- dizziness
- nausea
- cold sweats
- memory and thinking problems; difficulty with learning new things, concentrating, or making decisions

5. What should I know while using Phenergan?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using Phenergan.

Phenergan may cause your skin to be more sensitive to the sun. You should protect your skin from exposure to bright sunlight.

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

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 should not do

- Do not give Phenergan to anyone else, even if they have the same condition as you.
- Do not take Phenergan to treat any other complaints unless your pharmacist or doctor tells you to.
- Do not take more than the recommended dose unless your pharmacist or doctor tells you to.

Things to be careful of

- Phenergan is a known sedative and may cause drowsiness in some people.
- If you have a single dose at bedtime, you may still be affected in the morning.
- Children and the elderly are especially sensitive to the effects of antihistamines.

Neuroleptic malignant syndrome

A very serious and sometimes deadly 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.

Driving or using machines

Phenergan can cause drowsiness, dizziness and blurred vision. Make sure you know how you react to Phenergan before you drive a car, operate machinery, or do anything else that could be dangerous if you experience drowsiness, dizziness and blurred vision. If this occurs do not drive or operate machinery.

Be careful before you drive or use any machines or tools until you know how Phenergan affects you.

Phenergan may affect your ability to drive a car or operate machinery or do anything else that could be dangerous if you are drowsy, dizzy or experience blurred vision. If this occurs do not drive or operate machinery.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Do not drink alcohol while taking Phenergan.

The sedation effects of alcohol may be increased.

Looking after your medicine

- 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.
- Store Phenergan tablets below 30°C.
- Store Phenergan elixir below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

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.

Keep it where young children cannot reach it, in a locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines

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, most of them 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.

Less serious side effects

Less serious side effects	What to do
General • dry mouth, nose & throat **Nervous system-related** • tiredness or sleepiness • headache • involuntary muscle movements (dystonia) **Mental** • nightmares in children • restlessness • confusion • anxiety • aggression • hallucination **Gastrointestinal** • stomach upset • loss of appetite • nausea or vomiting • diarrhoea or constipation **Eye disorders** • blurred vision **Respiratory** • congested nose **Skin-related** • increased sensitivity of the skin to sun	**Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.**

These are mild side effects of the medicine and are short-lived.

Serious/rare side effects

Serious side effects	What to do
General • fever • excessive sweating • dizziness • nausea • cold sweats • low blood pressure • shortness of breath **Urinary** • difficulty passing urine **Heart** • irregular heart beat • very fast or forceful heartbeats (palpitations) • chest pain • rapid pulse **Blood and Lymphatic System Disorders** • eosinophilia which is an increase in the number of eosinophils (a type of white blood cells) found in the blood test. • Thrombocytopenia which is a decrease in the number of platelets (cells in the blood that help with clotting) found in a blood test, which can lead to bleeding and bruising **Allergy related** • difficulty breathing **Liver-related** • jaundice - yellow tinge to skin or eyes **Nervous system-related** • tremors or convulsions • tinnitus - buzzing, hissing, ringing or other persistent noise in the ears • confusion • twitching or jerking muscles • dizziness, lightheadedness • severe headache • muscle cramps or stiffness • psychomotor hyperactivity **Central nervous system-related** • anxiety • seizures (fits) • hallucinations • agitation • nervousness and irritability	**Call your doctor straight away if you notice any of these serious side effects.**

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

Very serious side effects	What to do
Allergy related • wheezing or difficulty breathing • swelling of the face, lips, tongue or other parts of the body/severe allergic reaction where adrenalise is required for treatment (anaphylaxis) • skin rashes	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

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

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 or Medsafe in New Zealand https://www.medsafe.govt.nz/safety/report-a-problem.asp#Medicine. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

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

What Phenergan Tablets contain

Active ingredient (main ingredient)	• 10mg tablets - 10mg of promethazine hydrochloride per tablet • 25mg tablets - 25mg of promethazine hydrochloride per tablet
Other ingredients (inactive ingredients)	• lactose monohydrate • maize starch • povidone • magnesium stearate • hypromellose • macrogol 200 • Opaspray Blue M-1-4210A
Potential allergens	Contains sugars as lactose

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

What Phenergan Elixir contains

Active ingredient (main ingredient)	• 1mg/mL of promethazine hydrochloride
Other ingredients (inactive ingredients)	• maltitol solution • acesulfame potassium • sodium benzoate • sodium citrate dihydrate • citric acid monohydrate • sodium sulfite • sodium metabisulfite • ascorbic acid • caramel • orange juice flavour 510844E

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

What Phenergan looks like

Phenergan Tablets are available in two strengths:

- 10mg – circular, film-coated biconvex tablets with bevelled edges, pale blue in colour, one face impressed 'PN' above '10', the reverse face plain.
- 25mg - circular, film-coated biconvex tablets with bevelled edges, pale blue in colour, one face impressed 'PN' above '25', the reverse face plain.

Both tablet strengths are available in blister packs of 50 tablets and 25 tablets (New Zealand only).

Phenergan Elixir is a clear, bright, golden, syrupy liquid. Phenergan elixir is available in a 100mL bottle

Australian Registration Numbers

Phenergan 10mg tablets

AUST R 80159

Phenergan 25mg tablets

AUST R 80160

Phenergan Elixir 1mg/mL

AUST R 61576

Who distributes Phenergan

Phenergan Tablets and Elixir are supplied in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

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