

APOHEALTH Promethazine 10 Antihistamine for Allergy Relief and APOHEALTH Promethazine 25 Antihistamine for Allergy relief

Promethazine hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about APOHEALTH Promethazine Antihistamine for Allergy Relief.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

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

Keep this leaflet with the medicine.

You may need to read it again.

What APOHEALTH Promethazine Antihistamine for Allergy Relief is used for

APOHEALTH Promethazine Antihistamine for Allergy Relief 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 chickenpox 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 the body is allergic to.

Your doctor or pharmacist may have recommended it for another reason.

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

Before you take APOHEALTH Promethazine Antihistamine for Allergy Relief

When you must not take it

Do not take APOHEALTH Promethazine Antihistamine for

Allergy Relief if you have an allergy to:

- any medicine containing promethazine hydrochloride, medicines of similar properties or belonging to the specific family of chemicals called phenothiazines, other phenothiazines.
- 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.

Any person who is unconscious or in a coma must not be treated with Promethazine Antihistamine for Allergy Relief

Do not take APOHEALTH Promethazine Antihistamine for Allergy Relief if you are also taking monoamine oxidase inhibitors, a type of medicine used to treat depression.

Do not take APOHEALTH Promethazine Antihistamine for Allergy Relief if you have jaundice.

Do not take this medicine 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).

Do not take this medicine if you have slowed breathing or heart rate of any cause.

Any person who is unconscious or in a coma must not be treated with APOHEALTH Promethazine Antihistamine for Allergy Relief.

Do not give APOHEALTH Promethazine Antihistamine for Allergy Relief to newborn or premature babies.

Do not give to children under six years of age, due to the potential for fatal respiratory depression.

Do not take APOHEALTH Promethazine Antihistamine for Allergy Relief if you are breastfeeding or planning to breastfeed.

It passes into the breast milk and there is a possibility that the baby may be affected.

Do not take APOHEALTH Promethazine Antihistamine for Allergy Relief 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 APOHEALTH Promethazine Antihistamine for Allergy Relief if the packaging is torn or shows signs of tampering.

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 or pharmacist if you 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 white 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

Tell your doctor or pharmacist if you plan to have surgery.

Tell your doctor or pharmacist if you 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 APOHEALTH Promethazine Antihistamine for Allergy Relief due 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.

Check with your doctor or pharmacist if you are a woman of childbearing age and not using effective contraception.

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

APOHEALTH Promethazine Antihistamine for Allergy Relief is not recommended for use during pregnancy. It may affect your developing baby if you take it

during pregnancy. If there is a need to consider APOHEALTH Promethazine Antihistamine for Allergy Relief during pregnancy, your doctor or pharmacist will discuss with you the benefits and risks of taking it

Taking other medicines

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

Some medicines and APOHEALTH Promethazine Antihistamine for Allergy Relief may interfere with each other. APOHEALTH Promethazine Antihistamine for Allergy Relief 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 and 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 used for the treatment of epilepsy or seizures
- Medicine 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 APOHEALTH Promethazine Antihistamine for Allergy Relief or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

How to take APOHEALTH Promethazine Antihistamine for Allergy Relief

How much to take

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

They may differ from the information contained in this leaflet.

APOHEALTH Promethazine Antihistamine for Allergy Relief tablets are recommended for adults and children over 6 years of age.

APOHEALTH Promethazine Antihistamine for Allergy Relief tablets should not be given to children aged between 6 and 11 years of age, except on the advice of your doctor or pharmacist.

It is recommended that the lowest effective dose of APOHEALTH Promethazine Antihistamine for Allergy Relief be used in children 6 years of age or older.

Allergic Disorder

Adults and children over 12 years of age: 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 as a single dose at night, or one 10mg tablet, two to three times daily.

Sedation

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

Adults and children over 12 years of age: One to three 25mg tablets as a single dose at night.

Children 6-12 years: One to two 10mg tablets as a single dose at night.

Travel Sickness

Adults and children over 12 years of age: One 25mg tablet.

Children 6-12 years: One 10mg tablet.

To be taken the night before travel and repeated after 6 to 8 hours on the following day if required.

Nausea and Vomiting

Adults and children over 12 years of age: One 25mg tablet every 4 to 6 hours to a maximum daily dose of four 25mg tablets (100 mg in total).

Children 6-12 years: One 10mg tablet every 4 to 6 hours to a maximum daily dose of two 10mg tablets (20 mg in total).

If you do not understand the instructions on the carton or label, ask your doctor or pharmacist 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 doctor or pharmacist about how much to take.

Elderly patients are more likely to have side effects from taking these medicines.

How to take it

Swallow APOHEALTH Promethazine Antihistamine for Allergy Relief whole with a full glass of water.

How long to take it

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

If you forget to take it

If you are taking APOHEALTH Promethazine Antihistamine for Allergy Relief 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 doctor or pharmacist.

If you are taking APOHEALTH Promethazine Antihistamine for Allergy Relief for travel sickness or nausea and vomiting, take your dose as soon as you remember.

If you are taking APOHEALTH Promethazine Antihistamine for Allergy Relief 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 doctor or pharmacist.

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 (telephone 13 11 26) 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 APOHEALTH Promethazine Antihistamine for Allergy Relief.

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

You may need urgent medical attention.

If you take too much APOHEALTH Promethazine Antihistamine for Allergy Relief, 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

While you are taking APOHEALTH Promethazine Antihistamine for Allergy Relief

Things you must do

APOHEALTH Promethazine Antihistamine for Allergy Relief may cause skin to be more sensitive to the sun. You should protect your skin from sun or exposure to bright sunlight.

Tell any other doctor, dentist or pharmacist who are treating you that you are taking APOHEALTH Promethazine Antihistamine for Allergy Relief.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking APOHEALTH Promethazine Antihistamine for Allergy Relief.

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 taking this medicine, stop taking it and tell your doctor immediately.

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

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

Things you must not do

Do not give APOHEALTH Promethazine Antihistamine for Allergy Relief to anyone else, even if they have the same condition as you.

Do not take APOHEALTH Promethazine Antihistamine for Allergy Relief to treat any other complaints unless your doctor or pharmacist tells you to.

Do not drink alcohol while taking APOHEALTH Promethazine Antihistamine for Allergy Relief. The sedation effects of alcohol may be increased.

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

Things to be careful of

APOHEALTH Promethazine Antihistamine for Allergy Relief is a known sedative and may cause drowsiness in some people.

Make sure you know how you react to APOHEALTH Promethazine Antihistamine for Allergy Relief 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.

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 while taking APOHEALTH Promethazine Antihistamine for Allergy Relief. The sedation effects of alcohol may be increased.

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

Side effects

APOHEALTH Promethazine Antihistamine for Allergy Relief 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 side effects.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking APOHEALTH Promethazine Antihistamine for Allergy Relief.

Tell your doctor or pharmacist 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
- confusion
- anxiety
- blurred vision
- congested nose
- headache
- involuntary muscle movement (dystonia)
- nightmares in children
- increased sensitivity to the sun
- dizziness

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

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

- fever
- excessive sweating
- dizziness
- nausea
- cold sweats
- low blood pressure
- difficulty breathing
- difficulty passing urine
- irregular heartbeat
- 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 (thrombocytopenic purpura)

- jaundice – yellow tinge to the skin or eyes
- 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
- anxiety
- agitation
- seizures (fits)
- hallucinations
- agitation
- nervousness and irritability
- neuroleptic malignant syndrome (NMS) – see subheading “Things to be careful of”
- severe uncontrollable muscular movements

The above list includes serious side effects that may require medical attention. These side effects are 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/severe allergic reaction where adrenaline is required for treatment (anaphylaxis)
- skin rashes

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

Tell your doctor or pharmacist 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 doctor or pharmacist if you have any questions.

After using APOHEALTH Promethazine Antihistamine for Allergy Relief

Storage

Keep your medicine in the original container 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 30°C.

Do not store APOHEALTH Promethazine Antihistamine for Allergy Relief 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 the medicine where children cannot reach it.

A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking APOHEALTH Promethazine Antihistamine for Allergy Relief or if it has passed the expiry date, ask your pharmacist what to do with any medicine you have left over.

Product description

What it looks like

APOHEALTH Promethazine 10
Antihistamine for Allergy Relief
tablets:

- 10 mg tablets – round, white to off-white, flat faced, beveled-edged tablets, debossed 10 on one side and plain on the reverse side.

APOHEALTH Promethazine 25
Antihistamine for Allergy relief
tablets:

- 25 mg tablets – round, white to off-white, flat faced, beveled-edged tablets, debossed 25 on one side and plain on the reverse side.

Both are available in blister packs of 50 tablets.

Ingredients

Active ingredient:

- 10 mg tablets – 10 mg of promethazine hydrochloride
- 25 mg tablets – 25 mg of promethazine hydrochloride

Inactive ingredients:

- magnesium stearate
- microcelac-100 (containing lactose monohydrate & microcrystalline cellulose)

Contains sugars as lactose.

Supplier

Arrotex Pharmaceuticals Pty Ltd
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