

PHARMANIAGA PROMETHAZINE SYRUP

Promethazine Hydrochloride (5mg/5ml)

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What Pharmaniaga Promethazine Syrup is used for

Pharmaniaga Promethazine Syrup is used:

- for relieving allergy symptoms, hay fever and skin disorders.
- for motion sickness, nausea and vomiting associated with morning sickness.
- to treat pain after surgery
- to treat drug intolerance (drug sensitivity)

How Pharmaniaga Promethazine Syrup works

Pharmaniaga Promethazine Syrup contains phenothiazine antihistamine. Phenothiazine works by blocking histamine, which decreases the symptoms of allergies and helps decrease nausea and vomiting.

Before you use Pharmaniaga Promethazine Syrup Tablet

- When you must not take it

Do not take Pharmaniaga Promethazine Syrup if you:

- are allergic to any medicine containing promethazine

- have severe central nervous system depression or are in a coma
- are taking or have taken in the last two weeks monoamine oxidase inhibitors (MAOIs) prescribed for depression.

Pharmaniaga Promethazine Syrup should not be used in children younger than 2 years old. Potential fatal side effects (eg. difficult or slowed breathing, drowsiness leading to coma) may occur in this age group when taking promethazine syrup.

Use carefully and follow the advice from doctor or pharmacist for children aged 2 to 6 years old.

- Before you start to use it

Some medical conditions may interact with Pharmaniaga Promethazine Syrup. Tell your doctor or pharmacist if you have any medical conditions, especially if any of the following apply to you:

- if you are pregnant, planning to become pregnant, or are breast-feeding. Your doctor or pharmacist can discuss with you the risks and benefits involved.
- if you are taking any prescription or nonprescription medicine, herbal preparation, or dietary supplement
- if you have allergies to medicines, foods, or other substances
- if you have history of heart problems, glaucoma (increased eye pressure), liver problems, an enlarged prostate, seizures, asthma bronchitis (inflammation of the lining in the airway), bronchiectasis (permanent enlargement of parts of the airways of the lung), severe coronary artery disease (heart disease), epilepsy and kidney insufficiency.
- if you regularly consume large amounts of alcohol

- Taking other medicines

Inform your doctor or pharmacist if you are taking any medicines, including ones you get without a prescription from your pharmacy, supermarket or health food shops. Some medicines may interact with Pharmaniaga Promethazine Syrup.

Tell your doctor or pharmacist if you are taking any other medicines, especially any of the following:

- CNS depressants (eg. alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquilisers)
- monoamine oxidase inhibitors (MAOIs) (eg. phenelzine)
- anticholinergics (medicine for abdominal or stomach spasms or cramps) or other medications with anticholinergic activities (including maprotiline or tricyclic antidepressants)
- medicines having toxic effects on the organs of hearing and balance e.g aspirin
- anti diarrhoeals and antiperistaltic agents
- hydroxyzine
- levodopa
- this medication may produce dry mouth, thus diminishing the efficacy of drugs administered by the sublingual route such as glyceryl trinitrate

This may not be a complete list of all interactions that may occur. Ask your health care provider if promethazine syrup may interact with other medicines that you take. Check with your health care provider before you start, stop, or change the dose of any medicine.

How to take Pharmaniaga Promethazine Syrup

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

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They may differ from the information contained in this leaflet.

If you do not understand the directions on your prescription bottle, consult your pharmacist, nurse, or doctor to explain the instructions to you.

- How much to use

Use a measuring device marked for medicine dosing. Ask your pharmacist for help if you are unsure on how to measure your dose.

For children 2-5 years:

Take 1 teaspoonful every 12 hours or every 8 hours

For children 6-12 years:

Take 1-2 teaspoonfuls every 12 hours or every 8 hours

For children under 2 years:

Not recommended to give to this group of children

- When to use it

Take promethazine syrup by mouth. Follow the direction label carefully.

- How long to use it

Continue consuming your medicine for as long as your doctor tells you. This medicine is usually only used for a short period of time. If symptoms persist, consult your doctor.

- If you forget to take it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take extra medicine to make up the missed dose.

- If you take too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your

nearest hospital. If you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of overdose with promethazine include: drowsiness, mild hypotension (low blood pressure), large doses cause severe postural hypotension (drop in blood pressure due to a change in body position), tachycardia (increased heart rate), dryness of mouth, nausea, fever, stiffness of muscle, urinary retention and coma.

While you are using Pharmaniaga Promethazine Syrup

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Pharmaniaga Promethazine Syrup.

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 take Pharmaniaga Promethazine Syrup to treat any other complications unless your pharmacist or doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

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

Do not drink alcohol or use medicines that may cause drowsiness (eg. sleep aids, muscle relaxers) while you are using Pharmaniaga Promethazine Syrup, as it may add to their effects. Ask your pharmacist if you have questions regarding medicines that may cause drowsiness.

Do not use if you are hypersensitive to bisulphite.

- Things to be careful of

Be careful when driving or operating any machineries, until you know how Pharmaniaga Promethazine Syrup affects you.

Promethazine syrup may cause drowsiness and dulling of mental alertness. If you are taking these medicine, you should not take charge of vehicles, other means of transportation or machineries where loss of attention may lead to accidents.

Children receiving Promethazine should be closely supervised while performing hazardous activities such as bike riding. It should not be used in premature babies or newborns. Use with caution in children with a history of sleep apnoea (pause in breathing during sleep), those with a family history of SIDA (Sudden Infant Death Syndrome) and those who are less prone than usual to spontaneous arousal from sleep.

Side effects

Tell your pharmacist or doctor if you feel unwell while taking Pharmaniaga Promethazine Syrup. This medicine helps most people, but it may have unwanted side effects in few people. All medicines have adverse side effects. Sometimes they are serious, most of the time they are not. You may need

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medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Check with your doctor if any of these most **COMMON** side effects persist or become bothersome:

- Blurred vision; dizziness; drowsiness; dry mouth

This is not a complete list of all side effects that may occur. If you have questions regarding the side effects, please contact your health care provider. Call your doctor for medical advice about side effects.

You may report any side effect or adverse drug reaction directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel :03-7883 5550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and disposal of Pharmaniaga Promethazine Syrup

- Storage

Keep the medicines in a cool dry place where the temperature stays below 25°C. Protect from light.

Do not store it or any other medicine in the bathroom, or near a sink, or on a window sill.

Do not leave it in the car on hot days. Heat and dampness can destroy some medicines.

Do not use this medication after the expiry date which is printed on the product packaging. The expiry date refers to the last day of that month.

Keep it where children cannot reach it.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

- What it looks like

Clear mixture, light brown in colour and with prune flavor.

- Ingredients:

- Active ingredients:

Pharmaniaga Promethazine Syrup
5mg/5ml contains (per 5ml)
Promethazine Hydrochloride 5mg

- Inactive ingredients:

Sodium Metabisulfite, Liquid Caramel, Purified Water, Sugar, Sodium Sulphate Anhydrous, Ascorbic Acid, Prune Extract, Benzoic Acid, Sodium Saccharin and Xanthan Gum.

MAL Number:

MAL20000219AZ

Manufacturer:

Pharmaniaga Manufacturing Berhad (60016-D),
11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

Product Registration Holder:

Pharmaniaga Manufacturing Berhad (60016-D),
11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

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