

PROMETHAZINE SYRUP

Promethazine hydrochloride (5mg/5ml and 10mg/5ml)

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1. What Promethazine syrup is used for

- To relief of excessive secretion in upper respiratory tract and coryza (catarrhal inflammation of the mucous membrane in the nose, caused especially by a cold or by hay fever) with watery eyes arising from upper respiratory tract infection.
- To treat hayfever, vasomotor rhinorrhoea (non-allergic runny nose, sneezing, and nasal stuffiness) allergic skin condition including urticaria (a rash of round, red weals on the skin which itch intensely) and angioneurotic edema (type of swelling that affects deeper layers in your skin, often around your eyes and lips), drug sensitisation reactions (due to penicillin and other antibiotics, barbiturates, sulphonamides)
- As a sedative and hypnotic in insomnia (is a sleep disorder that is characterized by difficulty falling and/or staying asleep), mental and emotional disturbances.
- As an antiemetic (to treat nausea and vomiting) in motion sickness and nausea and vomiting due to other

causes including postoperative sickness, pregnancy sickness.

- As a sedative for infants and children including those who are restless, irritable, anxious, emotionally upset or tooting, to relief itching in measles and chickenpox

2. How Promethazine syrup works

This medicine belongs to a group of medicines called phenothiazines. It works by blocking a natural substance (histamine) that your body makes during an allergic reaction. It also works directly on the brain to help you feel more relaxed.

3. Before you use Promethazine syrup

When you must not use it

Do not take this medicine and tell your doctor if:

- You have eczema or tendency to rheumatism (painful inflammation in muscles, joints, or connective tissue).
- You have jaundice caused by other phenothiazine derivatives.
- You are allergic (hypersensitive) to promethazine hydrochloride or any of the other ingredients in this medicine.

If you are not sure please ask your doctor or pharmacist. Do not take this medicine if any of the above applies to you.

Before you start to use it

Tell your doctor or pharmacist if you have any medical conditions, especially if any of the following apply to you:

- You have eczema
- You have tendency to rheumatism (pain in the joints and muscles)
- If you have jaundice.
- If you are pregnant.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you can buy without prescription, including herbal medicines. This is because Promethazine Hydrochloride can affect the way some medicines work. Also some medicine can affect the way Promethazine Hydrochloride works.

4. How to take Promethazine syrup

How much to take

Promethazine exerts its hypnotic (to induce sleep) effects for 8 to 12 hours but its antihistamine action persists much longer.

To be taken orally, in divided doses or as a single dose at night, the following:

Adults: up to 75 mg

Children:

6 – 12 years : 10 – 25 mg

2 – 5 years : 5 – 15 mg

When to take it

Use as directed by your doctor or pharmacist

How long to take it

Continue taking Promethazine syrup for as long as your doctor recommends

If you forget to take it

- Consult your doctor or pharmacist on what you should do if you forget to use 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 a double dose to make up for the missed dose.

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If you take too much (Overdose)

If you take more Promethazine Syrup than you should, tell your doctor or pharmacist. Take the medicine pack with you. This is so the doctor knows what you have taken. Also do this if a child under 2 years of age swallows some of this medicine.

The symptoms for overdose of Promethazine hydrochloride is unconsciousness, convulsions (an abnormal violent and involuntary contraction or series of contractions of the muscles), hallucinations, delirium (a temporary state of mental confusion and fluctuating consciousness), acute anxiety, extreme hyperaesthesia (abnormally increased sensitivity of the skin). It may also cause tachycardia (abnormally rapid heart rate), flushed skin (redness of the skin), dry mouth and sometimes mydriasis (dilation of the pupil of the eye).

5. While you are using Promethazine syrup

Things you must do

Pregnancy and breastfeeding
Please talk to your doctor while you are using this medicine if you are pregnant and breastfeeding. It is wise to take caution in using any medicine in the first trimester of pregnancy.

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking promethazine syrup.

Things you must not do

- Do not stop taking the medicine unless advised by your doctor.

- Do not take any new medicines without consulting your doctor.

- Do not give Promethazine syrup to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Driving and operating machinery
This may cause drowsiness in some people. If affected do not drive or operate machinery.

This medicine is not suitable to be used in children below 2 years old because of the potential for fatal respiratory depression (decreased rate of breathing which may cause death).

For children between 2 to 6 years old – use with caution and follow the advice given by the doctor or pharmacist.

6. Side effects

Like all medicines, Promethazine Syrup can cause side effects, although not everybody gets them.

- Daytime drowsiness
- Dizziness
- Slight disorientation
- Mild headache
- Twitching of the limbs at night
- Ataxia (the loss of full control of bodily movements)
- Nightmare

If you get any side effects, even those not mentioned in this leaflet, tell your doctor or pharmacist

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumer→Reporting)

7. Storage and disposal of Promethazine syrup

Storage

- Store below 25°C.
- Keep container tightly closed.

- Protect from light.

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.

8. Product description

What it looks like

A clear, light brown liquid.

Ingredients

Active ingredient
Promethazine hydrochloride.

Inactive ingredients
Refined sugar, purified water, methylparaben, chloroform spirit, raspberry flavour, mormel grade A (liquid caramel), citric acid, sodium saccharin.

MAL Number.

Promethazine syrup 5mg/5ml
MAL19861127AZ
Promethazine syrup 10mg/5ml
MAL19861133AZ

9. Manufacturer

Noripharma Sdn. Bhd.,
Lot 5030, Jalan Teratai, 5 ½ Mile off Jalan Meru,
41050 Klang, Selangor.

Product Registration Holder

Pahang Pharmacy Sdn.
Bhd.(10826-K)
Lot 5979 Jalan Teratai, 5½ Mile Off Jalan Meru, 41050 Klang Selangor Darul Ehsan. Malaysia

10. Date of revision

10/04/15

Serial number

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