

PROMENE TABLET

Promethazine Hydrochloride (25mg)

What is in the leaflet

1. What Promene Tablet is used for
2. How Promene Tablet works
3. Before you use Promene Tablet
4. How to use Promene Tablet
5. While you are using it
6. Side effects
7. Storage and disposal of Promene Tablet
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Promene Tablet is used for

Promene Tablet is used to

- relieve symptoms of allergy that causes sneezing, congestion, itchy nose and watery eyes (allergic rhinitis), hives, and also severe allergic reaction due to medication or foreign substances
- help in sedation before or after surgery or during childbirth (an additional treatment)
- prevent and reduce nausea and vomiting
- Short term use only:
- To help adults sleep if they have sleep difficulty (insomnia).
- To calm children when sedation is needed.

How Promene Tablet works

Promene Tablets contain a active ingredient promethazine hydrochloride. 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.

Before you use Promene Tablet

- When you must not use it

Do not take this medicine:

- if you are allergic to promethazine hydrochloride or any other ingredients of this medicine (listed in Product Description)
- your child is below 2 years old
- if you are taking medicine known as monoamine oxidase inhibitors (MAOIs) (for depression), or have taken such a medicine within the last 14days.

- Before you start to use it

Tell your doctor or pharmacist before you take this medicine if you:

- have asthma and difficulty in

breathing

- have increased pressure in the eye (glaucoma)
- have suffered from Reye's Syndrome (a rare illness in children/teens linked to viral infections).
- Have sugar intolerance as this product contains lactose
- have stomach or digestion problems like ulcers or blockage
- have prostate problems or difficulty passing urine
- drink alcohol
- heart disease or liver problems
- When used for treatment of cough and cold:

(a) Not to be used in children less than 2 years of age

(b) To be used with caution and doctor's / pharmacist's advice in children 2 to 6 years of age.

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breastfeeding before using any medicine.

Do not take promethazine in the last two weeks of pregnancy, as it may cause irritability and excitement in the baby. Only use this medicine during pregnancy if benefits outweigh the risks to the baby.

A very small amount of this medicine may pass into breast milk, but it is usually too little to cause harm. Always check with your doctor or pharmacist before using if you are breastfeeding.

Taking other medicines

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

Tell your doctor if you are taking:

- antidepressants
- Alcohol
- Sleeping pills
- Strong painkillers (opioid type)
- Sedatives / tranquilizers (medicines that calm or relax you)

- Barbiturates (a type of sleeping or calming medicine)

If you are going to undergo any procedures or surgery, tell your doctor or nurse that you are taking promethazine.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Promene Tablet.

How to use Promene Tablet

-How much to use

For allergic conditions:

Children 5-10 years old:
1 tablet as a single dose.

Children over 10 years old and adults (including elderly):

1 tablet as a single dose. Increasing to a maximum of 1 tablet twice daily as required.

For nausea and vomiting:

Children over 10 years old and adults (including elderly):

1 tablet to be taken the night before the journey. To be repeated after 6-8 hours as required.

Short term sedation:

Children 5-10 years
1 tablet as a single night time dose.

Children over 10 years and adults (including elderly)

1 to 2 tablet as a single night time dose.

This medicine is not for use in children under 2 years.

- When to use it

Single dose is best taken at night. Take as directed by your doctor or pharmacist.

- How long to use it

Take this medicine for the duration that your doctor recommends. Do not use for more than 7 days without consulting your doctor.

- 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 use too much (overdose)***

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you or anyone else may have used too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too much Promene can cause feeling very sleepy, dizzy, confused or faint, trouble breathing, very fast or slow heartbeat, shaking, stiff muscles, fits (seizures), dry mouth, flushed skin, large pupils, or unusual behaviour such as excitement, nightmares or hallucinations (especially in children). In severe cases, it can be life-threatening.

While you are using it

- ***Things you must do***

- Use your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are using Promene Tablet
- Tell your doctor immediately if you become pregnant while using this medication.

- ***Things you must not do***

- Do not use any new medicines without consulting your doctor or pharmacist.
- Do not give Promene Tablet to anyone else, even if they have the same symptoms or condition as you.
- Do not drink alcohol whilst taking this medicine.

- ***Things to be careful of***

Driving and using machines

You may feel drowsy or sleepy after taking this medicine or the morning after taking this medicine. If this happens, do not drive or use any tools or machines.

Promene Tablets may affect the results of certain tests. These include some pregnancy tests and skin tests. Stop taking Promene Tablet 3 days before a skin test.

Side effects

Like all medicines, Promene Tablet can cause side effects, although not everybody gets them. Possible side effects are:

Nervous system

- Feeling very sleepy or drowsy
- Blurred vision, dizziness, tiredness
- Confusion or disorientation
- Restlessness, nervousness, or trouble sleeping
- Tremors (shaking), loss of coordination, ringing in the ears
- Unusual movements (stiff neck, eyes rolling upwards, tongue sticking out)
- Seizures (fits)
- Hallucinations (seeing or hearing things that are not there)
- Rare: catatonic-like state, hysteria, extreme excitement

Heart

- Fast heartbeat (palpitations)
- Slow heartbeat
- Low or high blood pressure
- Fainting

Blood

- Low white blood cells (may increase risk of infection)
- Low platelets (may cause easy bruising or bleeding)
- Very rare: severe lack of certain blood cells (agranulocytosis)

Skin

- Rash or hives (red, itchy skin)
- Sensitivity to sunlight (skin burns easily)
- Allergic skin reactions (dermatitis)
- Swelling of face/lips/tongue (angioedema)

Digestive system

- Dry mouth
- Nausea or vomiting
- Yellowing of skin or eyes (jaundice – liver problem)

Respiratory

- Stuffy nose
- Asthma flare-up
- Breathing difficulty, slowed or stopped breathing (serious, may be fatal)

Other serious reactions (rare)

- episodic and unpredictable swellings of the skin, neuroleptic malignant syndrome (severe reaction with very high fever, stiff muscles, sweating, fast heartbeat – can be life threatening)

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of Promene Tablet

- ***Storage***

Store below 30°C.

- ***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***

A blue coloured round shaped film coated tablet

- ***Ingredients***

-Active ingredient:

Promethazine hydrochloride

- Inactive ingredients:

Lactose, corn starch, povidone, magnesium stearate, Hydroxypropyl methylcellulose, polyethylene glycol, Propylene glycol, talc, titanium dioxide, Brilliant Blue lake, isopropyl alcohol and purified water

- ***MAL number***

MAL12035006AZ

Manufacturer and Product Registration Holder

Noripharma Sdn. Bhd

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