

PROZINE SYRUP

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

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What Prozine Syrup is used for

Prozine Syrup is used as treatment for;

- dermatographism (skin becoming raised red lines after scratching).
- rhinitis (inflammation of the mucous membrane inside the nose).
- nausea and vomiting or as prevention with certain type of anaesthesia, in surgery or motion sickness.
- mild, uncomplicated allergic skin manifestations of hives and swelling of the deeper layers of the skin.
- as a sedative (to help people go to sleep and control their anxiety) before and after surgery, and during labour.
- improvement of allergic reactions to blood or plasma.
- allergic conjunctivitis (inflammation in eyes) due to allergens and foods.

How Prozine Syrup works

The active ingredient in the medicine is promethazine hydrochloride. Promethazine is an anti-histamine. It is capable of producing sedative effects. It works by blocking a certain natural substance (histamine) that your body makes during an allergic reaction.

Before you use Prozine Syrup

- When you must not use it

Do not take this medicine if you:

- are hypersensitive to promethazine, or any of the other ingredients listed at the end of the leaflet.
- have received large amounts of central nervous system (CNS) depressants (such as alcohol, barbiturate, opioid pain relievers).
- have asthma.

- Before you start to use it

Tell your doctor before taking this medicine if you have:

- closed-angle glaucoma (increase pressure in eyes).
- stomach or duodenal ulcer.
- enlargement of prostate or gastric outflow obstruction.
- bladder problems.
- bone marrow depression.

Pregnancy and breastfeeding

You should check with your doctor if you are or think you may be pregnant, planning to become pregnant or if you are breastfeeding.

It is not recommended for pregnant women and nursing mothers unless the expected benefit outweighs any potential risks.

There is inadequate evidence of safety in human pregnancy. Caution should be taken when breastfeeding.

Children

Should not be used for children under 2 years of age as safety has not been established.

- Taking other medicines

There are a few medicines which may interact with Prozine Syrup. It is important to tell your doctor or pharmacist about all the medicines that you are taking, including those obtained without doctor's prescription. You should talk to your doctor or pharmacist if you are taking:-

- Alcohol, antidepressants, barbiturates or other central nervous system (CNS) depressants.
- Opioid pain relievers such as morphine, meperidine.

How to use Prozine Syrup

- How much to use

You should take Prozine Syrup exactly as advised by your doctor or pharmacist. The amount you take each day will depend on your condition. Do not take more or less than what your doctor prescribes.

Oral administration.

Allergy

Adults: The initial dose is 25mg, taken before sleep. If necessary, 12.5mg can be taken before meals and before sleep.

Children above 2 years old: A single dose of 25mg is taken before sleep or 5mg to 15mg three times daily.

Dosage may adjusted to the smallest amount adequately to relief symptoms after the initiation of treatment in children (more than 2 years) or adults.

Motion sickness

Adult: The initial dose is 25mg taken twice daily taken half an hour or one hour before travel and be repeated 8 to 12 hours later, if necessary. On succeeding days of travel, 25mg to be given in the morning and again before the evening meal.

Children above 2 years old: 12.5mg to 25mg to be taken twice daily.

Antiemetic therapy

The initial dose 25mg is taken 4 to 6 hours interval as necessary.

Sedation

12.5mg to 25mg to be taken. For Adults, 25mg may required at night time, sedation before surgery, or during labour.

- When to use it

Use Prozine Syrup when needed and according to doctor's prescription.

- How long to use it

It is important to take Prozine Syrup as long as your doctor prescribes.

- 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.

- If you use 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 include low blood pressure, difficulty in breathing and unconsciousness, dry mouth, fixed dilated of eye pupil, flushing and gastrointestinal symptoms may occur.

While you are using it**- Things you must do**

- Tell all the doctors, dentists and pharmacists treating you that you are taking Prozine Syrup.
- Tell your doctor immediately if you become pregnant while taking this medication.

- 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 Prozine Syrup to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Promethazin may cause your ability to concentrate or react may be impaired. Be careful when driving a vehicle or operating a machine until you know the effect of Prozine Syrup on you.

Side effects

Like all medicines, Prozine Syrup can cause side effects, although not everybody gets them. Side effects such as dryness of mouth, vision blur, rarely dizziness, increase and mild low blood pressure may occasionally arise. Very rare case has been reported for low white blood cell, and sensitivity to light. Cardiovascular effects and convulsions from promethazine have been rare.

Besides this, side effects such deep sedation, coma, breathing problems has influence on taking promethazine. Paradoxical reactions nightmares, hyperexcitability has been reported in children that receiving single high dose.

Any other effects not listed above may also occur in some people. Please refer to your doctor or pharmacist if you experience any other side effects while taking this medication.

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 Prozine Syrup**- Storage**

Protect from light.

Prozine Syrup

Store at temperature 25°C.

Prozine 10 Syrup

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**

Prozine Syrup: A clear, light brown syrup with orange flavour.

Prozine 10 Syrup: A clear, brown syrup with blackcurrant flavour.

- Ingredient(s)

- Active Ingredient

- Promethazine hydrochloride

- Inactive Ingredients

Prozine Syrup

- Ascorbic Acid
- Citric Acid
- Liquid Caramel
- Sweet Orange
- Sodium Benzoate
- Deionised Water
- Syrup Simplex

Prozine 10 Syrup

- Ascorbic Acid
- Citric Acid
- Liquid Caramel
- Blackcurrant Flavour
- Sodium Benzoate
- Deionised Water
- Syrup Simplex

- MAL number

Prozine Syrup
MAL19990605AZ

Prozine 10 Syrup
MAL06071066AZ

Manufacturer

Sunward Pharmaceutical Sdn. Bhd.
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Product Registration Holder

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