

# PROEZINE SYRUP

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

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## What Proezine Syrup is used for

Proezine Syrup may be provided to you for use in the following situations:

- To treat allergic conditions such as to relief symptoms of rhinitis:
  - Inflammation of the mucous membrane inside the nose
  - itching
  - hives
  - dermatographism (writing on the skin)
  - swelling beneath the skin
  - eye inflammation
  - allergic condition to blood or plasma
- To treat or stop you feeling sick or vomiting such as travel sickness or vomiting due to medicine or after operation.
- To help you feel more relaxed before and after surgery and during labour.
- For short term use:
  - To treat adults with difficulty sleeping
  - As a sedative (calm or inducing sleep) for children

## How Proezine Syrup works

This medicine contains the active ingredient Promethazine which is an antihistamine.

Histamine is a chemical released into the body during an allergic reaction. It works by blocking the effects of histamine, calming down the body's allergic reaction and starting to relieve the symptoms.

It also works directly on the brain to help you feel more relaxed.

## Before you use Proezine Syrup

### - When you must not use it

Do not take this medicine if:

- You are hypersensitive to, or have had an allergic reaction to promethazine or any of the ingredients listed at the end of this leaflet.
- You are taking a class of medicine known as 'monoamine oxidase inhibitors' (MAOIs) (often taken for depression), or you have taken such a medicine within the last 14 days.
- You have glaucoma (increased eye pressure)
- You have central nervous system depression such as decreased breathing rate, heart rate
- Adolescents with symptoms suggestive of Reye's syndrome (Symptoms may include vomiting, personality changes, confusion, seizures, and loss of consciousness).
- You use in premature infants or neonates
- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it damage

### - Before you start to use it

You must tell your doctor if:

- you are pregnant or intend to become pregnant.

Promethazine taken within 2 weeks prior to delivery may inhibit blood clot in the newborn.

- you are breast-feeding or plan to breast-feed. The use of Proezine by nursing mother should be discouraged. (Antihistamine may inhibit lactation and may be secreted into breast milk).
- you have epilepsy, severe heart or liver problems, and pyloroduodenal obstruction (obstruction of pylorus of the stomach).
- You have difficulty urinary, prostate enlargement
- you are taking medicines to treat anxiety or help you to sleep
- you drink alcohol every day.

If you have not told your doctor about any of the above, tell them before you use Proezine Syrup.

### Warning:

- Promethazine should not be used in children less than 2 years of age because of the potential for fatal respiratory depression (slow and shallow breathing).
- To be used with caution and doctor's or pharmacist's advice in children 2 to 6 years of age.

### - 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. Some medicines may interfere with Proezine Syrup.

These include:

- monoamine oxidase inhibitors (MAOIs) (antidepressant) or tricyclic antidepressants

- medicines that cause drowsiness or sleepiness (sedatives, hypnotics, tranquilisers, barbiturates, opioid analgesics)
- dopamine
- ephedrine
- medicines that are toxic to the liver
- beta-blocker (for heart problems)
- levodopa (for Parkinson's disease)
- Riboflavin (Vitamin B2)
- neuroleptic

Other interactions not listed above may also occur.

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

### How to use Proezine Syrup

#### - How much to use

##### Proezine Syrup 5mg/5ml

*For allergic conditions:*

*Children 2-5 years old:*

5ml to 15ml as a single dose or 5ml twice daily. Maximum daily dose 15ml.

*Children 5-10 years old:*

10ml to 25ml as a single dose or 5ml to 10ml twice daily. Maximum daily dose 25ml.

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

Initially 10ml twice daily. Increasing to a maximum of 20ml three times daily as required.

*For nausea and spinning sensation:*

*Children 2-5 years old:*

5ml to be taken night before journey.

*Children 5-10 years old:*

10ml to be taken night before journey.

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

25ml to be taken night before journey.

Dose may be repeated 6-8 hours later if needed.

*Short term sedation:*

*Children 2-5 years old:*

15ml or 20ml as a single night time dose.

*Children 5-10 years:*

20ml or 25ml as a single night time dose.

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

25ml or 50ml as a single night time dose.

##### Proezine Syrup 10mg/5ml

*For allergic conditions:*

*Children 2-5 years old:*

2.5ml to 7.5ml as a single dose or 2.5ml twice daily. Maximum daily dose 7.5ml.

*Children 5-10 years old:*

5ml to 12.5ml as a single dose or 2.5ml to 5ml twice daily. Maximum daily dose 12.5ml.

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

Initially 5ml twice daily. Increasing to a maximum of 10ml three times daily as required.

*For nausea and spinning sensation:*

*Children 2-5 years old:*

2.5ml to be taken night before journey.

*Children 5-10 years old:*

5ml to be taken night before journey.

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

12.5ml to be taken night before journey.

Dose may be repeated 6-8 hours later if needed.

*Short term sedation:*

*Children 2-5 years old:*

7.5ml or 10ml as a single night time dose.

*Children 5-10 years old:*

10ml or 12.5ml as a single night time dose.

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

12.5ml or 25ml as a single night time dose.

Single doses are best taken at night. This medicine is not recommended for use in children under 2 years.

#### - When to use it

Proezine Syrup may be taken with food, water or milk to lessen gastric irritation. Use as directed by your doctor or pharmacy.

#### - How long to use it

Depending on the medical condition for which you require Proezine Syrup, your doctor may tell you to take it for a certain period of time.

#### - If you forget to use it

If you forget to take a dose, you can take it as soon as you remember and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose that you missed.

#### - If you use too much (overdose)

Symptoms of overdose:-

- severe dryness of mouth, nose or throat
- clumsiness or unsteadiness
- severe drowsiness
- flushing or redness of face
- shortness of breath or troubled breathing
- hallucinations
- seizures
- trouble in sleeping
- muscle spasms especially of neck and back
- restlessness
- shuffling walk

- jerky movements of head and face
- trembling and shaking of hands
- severe low blood pressure (feeling faint), low blood pressure may also occur in the elderly at usual dose.

Overdosage may be fatal especially in infants and children.

Telephone your doctor, or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much Proezine Syrup.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

#### While you are using it

##### - Things you must do

Promethazine hydrochloride may affect certain diagnostic test results such as urine pregnancy test. It is recommended that antihistamines be discontinued at least 72 hours before testing begins.

If you become pregnant while you are taking Proezine Syrup, tell your doctor immediately.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Proezine Syrup.

##### - Things you must not do

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

Do not use Proezine Syrup to treat any other complaints unless your doctor tells you to.

##### - Things to be careful of

Be careful driving or operating machinery until you know how Proezine Syrup affects you.

Proezine Syrup may cause drowsiness, dizziness and blurred vision in some people.

Avoid alcohol drinking. Proezine Syrup will add the effects of alcohol.

Prolonged use of antihistamines may decrease or inhibit salivary flow, especially in middle-aged or elderly person.

#### Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking this medicine. Do not be alarmed by the following lists of side effects.

You may not experience any of them.

Tell your doctor if you notice any of the following and they worry you.

- drowsiness
- dizziness
- dry mouth, throat and nose are more likely to occur in the elderly.
- thickening of mucus in nose or throat
- blurred vision
- difficult or painful urination
- increased heart rate
- Nightmares; unusual excitement, nervousness, restlessness, or irritability are more likely to occur in children and elderly.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Monitoring by calling Tel: 03-78835549, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) (Public → [Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]).

#### Storage and disposal of Proezine Syrup

##### - Storage

Keep the medicine in a dry place where the temperature stays below 30°C. Protect from light. Keep container tightly closed.

Keep Proezine Syrup 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

Ask your pharmacist what to do with any medicine you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.

Medicines should not be disposed of via wastewater or household waste. These measures will help to protect the environment.

#### Product Description

##### - What it looks like

Proezine Syrup 5mg/5ml:

A brown, lemon flavoured syrup.

Proezine Syrup 10mg/5ml:  
A light brown, lemon  
flavoured syrup.

- Ingredients

- *Active ingredient:*

Proezine Syrup 5mg/5ml:  
Each 5ml contains 5mg of  
Promethazine hydrochloride

Proezine Syrup 10mg/5ml:  
Each 5ml contains 10mg of  
Promethazine hydrochloride

- *Inactive ingredients:*

- Preservatives  
(methylparaben and  
propylparaben
- lemon essence
- ascorbic acid
- liquid caramel
- refined sugar
- purified water

Proezine Syrup 5mg/5ml:

- sweet orange essence

- MAL number

Proezine Syrup 5mg/5ml  
MAL19860110AZ

Proezine Syrup 10mg/5ml  
MAL19860112AZ

**Manufacturer**

Upha Pharmaceutical Mfg. (M)  
Sdn Bhd (53667-M)  
Lot 2&4, Jalan P/7, Section 13,  
Bangi Industrial Estate,  
43650 Bandar Baru Bangi,  
Selangor Darul Ehsan.

**Product Registration Holder**

Upha Pharmaceutical Mfg. (M)  
Sdn Bhd (53667-M)  
Lot 2&4, Jalan P/7, Section 13,  
Bangi Industrial Estate,  
43650 Bandar Baru Bangi,  
Selangor Darul Ehsan.

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