

PROEZINE FILM COATED TABLET

Promethazine hydrochloride (25mg)

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What Proezine Tablet is used for

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

- To treat allergic conditions of the upper respiratory tract and skin such as to relief symptoms of perennial (throughout the year) and seasonal rhinitis (inflammation of the mucous membrane inside the nose), hives.
- 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 Tablet 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 Tablet

- 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 have glaucoma (increased eye pressure)
- you have central nervous system depression such as decreased breathing rate, heart rate
- You use in premature infants or neonates
- 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.
- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or 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 are taking medicines to treat anxiety or help you to sleep
- you have difficulty urinary, prostate enlargement
- you drink alcohol every day.

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

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 Tablet.

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 Tablet.

How to use Proezine Tablet

- How much to use

For allergic conditions:

Children 5-10 years old:

1 tablet as a single dose.

Maximum daily dose 1 tablet.

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.

As antiemetic (prevent vomit):

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.

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

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Depending on the medical condition for which you require Proezine Tablet, 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: -
- clumsiness or unsteadiness
- severe drowsiness;

- severe dryness of mouth, nose, or throat
- flushing or redness of face
- shortness of breath or troubled breathing
- hallucinations (hear, smell, taste or feel things that do not exist)
- 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 Tablet.

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 12 hours before testing begins

If you become pregnant while you are taking Proezine Tablet, 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 Tablet.

- Things you must not do

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

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

Do not drink alcohol whilst taking this medicine.

- Things to be careful of

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

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

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

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 heartrate
- 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 Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of Proezine Tablet

- Storage

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

Keep Proezine Tablet 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

A 6.5mm round convex core tablet, film coated blue, one side marked 'UP' and scored, the other side plain.

- Ingredients

- Active ingredient:
Each tablet of Proezine Tablet contains 25mg of Promethazine hydrochloride.

- Inactive ingredients:
- magnesium stearate
 - lactose monohydrate
 - sodium starchglycolate
 - opadry II blue
 - microcrystalline cellulose

- MAL number
MAL06061699AZ

Manufacturer

Duopharma Manufacturing (Bangi) Sdn Bhd
Lot 2&4, Jalan P/7, Section 13, Bangi Industrial Estate, 43650 Bandar Baru Bangi, Selangor Darul Ehsan.

Product Registration Holder

Duopharma Marketing Sdn. Bhd.
Lot 2,4,6,8&10 Jalan P/7, Section 13, Bangi Industrial Estate, 43650 Bandar Baru Bangi, Selangor Darul Ehsan.

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