

PROLIDIN TABLET/ SYRUP

Triprolidine hydrochloride/Pseudoephedrine hydrochloride (2.5mg/60mg, 1.25mg/30mg per 5ml)

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What PROLIDIN is used for

PROLIDIN is used for the temporary relief of nasal and sinus congestion, sneezing and runny nose associated with the common cold and allergic rhinitis (inflammation of the mucous membrane inside the nose).

How PROLIDIN works

Triprolidine hydrochloride is an antihistamine which works by blocking a certain natural substance (histamine) that your body makes during an allergic reaction. The antimuscarinic action provides a drying effect on the lining of nasal cavity.

Pseudoephedrine hydrochloride is a decongestant. It works by narrowing the blood vessels to decrease swelling and congestion

Before you use PROLIDIN

- When you must not use it

Do not use PROLIDIN if:

- You are allergic or hypersensitive to any ingredients in this product.
- You are being treated with monoamine oxidase inhibitors (MAOIs) for depression.
- Use of antihistamines in new-born or premature infants as they have higher risk to antimuscarinic effects, such as Central Nervous System excitation and convulsion.
- You have blood clot inside a blood vessel of the heart.
- You have excessive amount of thyroid hormones.

Pregnancy and lactation

Tell your doctor or pharmacist if you are pregnant, planning to get pregnant or breastfeeding. Use is not recommended during breastfeeding due to the risk of excitement or irritability in infants. Antihistamines may block the milk production. Ask your doctor for advice before using any medicines.

- Before you start to use it

Tell your doctor or pharmacist before using this medicine if you have any of the following:

- Heart disease
- High blood pressure
- Diabetes
- Intolerant of other similar medicines.

- Taking other medicines

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

These include:

- Tricyclic antidepressants
- Beta blockers (to lower high blood pressure)
- Anxiolytics (to relieve anxiety) and hypnotics (to induce sleep)
- Betahistine (to reduce spinning sensation)

How to use PROLIDIN

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

PROLIDIN SYRUP

Adults and children over 12 years: 2 teaspoonfuls (10 ml).

Children 7 - 12 years: 1 teaspoonful (5 ml).

Children 2 - 6 years: ½ teaspoonful (2.5 ml).

All to be taken 4 to 6 hourly.

WARNING (when used for treatment of cough and cold):

1. Not to be used in children less than 2 years of age.
2. To be used with caution and doctor's advice in children 2 to 6 years of age.

PROLIDIN TABLET

Adults and children over 12 years: 1 tablet.

Children 7 - 12 years: ½ tablet.

All to be taken 3 times daily.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking PROLIDIN for as long as your doctor recommends.

- If you forget to use 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.

- 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.

Taking too many tablets or too much syrup may cause drowsiness, lethargy, dizziness, ataxia (loss of muscle control and balance), weakness, a deficiency of muscle tone, slow respiratory rate, dryness of the skin and mucous membranes, tachycardia (heart rate that exceeds the normal resting rate), high blood pressure, high fever, hyperactivity, irritability, convulsions, difficulty in urination. In severe overdosage, apnoea (absence of breathing for short periods), circulatory collapse (failure of the circulation, either is in the heart or peripheral in nature.), cardiac arrest (heart suddenly and unexpectedly stops beating) and death may occur.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

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

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 or pharmacist.

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

- Things to be careful of

PROLIDIN may cause drowsiness. If affected, you should not drive or operate machinery.

Avoid consuming alcohol.

Prolonged use of antihistamines may decrease or block salivary flow, contributing to the development of caries, periodontal (gum) disease, oral candidiasis (fungal infection of the mouth) and discomfort.

Side effects

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

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

The side effects are drowsiness, dizziness, muscular weakness, gastrointestinal disturbances. It may raise the blood pressure. Individuals with enlargement of prostate may give rise to urinary retention. Sore throat, fever, unusual bleeding or bruising, unusual tiredness or weakness, tightness in chest, fast or irregular heartbeat, mood or mental changes, clumsiness or unsteadiness, dryness of mouth, nose, throat, severe or flushing or redness of face, shortness of breath, hallucinations (an experience in which you see, hear, feel, or smell something that does not exist), seizures, trouble in sleeping, headache.

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 calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of PROLIDIN

- Storage

Keep out of the reach and sight of children.

Keep container tightly closed

Store in dry place below 25°C

Protect from light

SHAKE WELL BEFORE USE

- 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

PROLIDIN SYRUP

Red colour syrup cherry flavor

PROLIDIN TABLET

Round, Biconvex and Scored White

Colour TABLET

- Ingredients

- Active ingredient(s)

Triprolidine hydrochloride & Pseudoephedrine hydrochloride

- Inactive ingredients

PROLIDIN SYRUP

Sugar, Liquid Glucose, Methyl Paraben, Propyl Paraben, Chloroform Spirit, Sodium Benzoate, Sodium Saccharin, Citric Acid, Menthol Crystals, Xanthan Gum (Rhodigel), Cherry Flavour, Red Raspberry

PROLIDIN TABLET

Lactose Powder, Starch, Gelatin, Aerosil, Magnesium Stearate

- MAL numbers:

PROLIDIN SYRUP

MAL19910177AZ

PROLIDIN TABLET

MAL19920509AZ

Manufacturer and Product

Registration Holder

Dynapharm (M) Sdn. Bhd
2497, Mukim 1, Lorong Perusahaan Baru 5, Kawasan Perusahaan Perai 3, 13600 Perai, Pulau Pinang, Malaysia.

Date of revision

28/06/2017