

POLARINE TABLET

Dexchlorpheniramine maleate/Pseudoephedrine hydrochloride (2mg/60mg)

What is in this leaflet

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

What Polarine Tablet is used for

It is indicated for nasal and upper respiratory tract congestion, common cold, acute sinusitis (inflammation of the sinuses) and allergic rhinitis (inflammation of the mucous membrane inside the nose).

How Polarine Tablet works

The active ingredients in the medicine are Dexchlorpheniramine maleate and Pseudoephedrine hydrochloride. Dexchlorpheniramine maleate is anti-histamine with anti-cholinergic properties. It works by blocking a certain natural substance (histamine) that your body makes during an allergic reaction. By blocking another natural substance made by your body (acetylcholine), it helps dry up some body fluids to relieve symptoms such as watery eyes and runny nose.

Pseudoephedrine acts as an indirect sympathomimetic agent by stimulating sympathetic (adrenergic) nerve endings to release norepinephrine. Pseudoephedrine belongs to a class of medications called nasal decongestants. It works by causing narrowing of the blood vessels in the nasal passages to decrease swelling and congestion.

Before you use Polarine Tablet

- When you must not use it

Do not take Polarine Tablet if you:

- are hypersensitive to any of the ingredients
- have lower respiratory symptoms
- severe high blood pressure
- severe heart disease

Pregnancy and breastfeeding

Tell your doctor if you are or think you may be pregnant, planning to become pregnant or if you are breastfeeding.

Elderly

Antihistamines may cause dizziness, sedation and low blood pressure in elderly above 60 years.

- Before you start to use it

Inform your doctor before using Polarine Tablet if you have any of the following:

- high blood pressure
- overactive thyroid
- diabetes
- cardiovascular disease (disease of the heart or blood vessels)
- narrow angle glaucoma (increased pressure inside the eye)
- stenosing peptic ulcer (swelling due to ulcers causes narrowing in the duodenum)
- pyloroduodenal obstruction (gastric outflow obstruction)
- enlargement of prostate
- bladder neck obstruction

Polarine Tablet is not recommended for children below 2 years. It should be used with caution and on doctor's or pharmacist's advice in children 2 to 6 years of age.

- Taking other medicines

There are a few medicines which may interact with Polarine Tablet. 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 on the following;

- Central Nervous System (CNS) depressants such as hypnotics, sedatives and tranquilizers
- Alcohol
- Monoamine Oxidase Inhibitors (MAOIs) for depression
- Methyldopa, Mecamylamine, Reserpine and Veratrum Alkaloids for high blood pressure

How to use Polarine Tablet

- How much to use

You should take Polarine Tablet 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.

For Adults: One tablet three times daily

For Children 6 to 12 years: Half a tablet three times daily.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

It is important to take Polarine Tablet 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.

Over dosage symptoms may include dry mouth, fixed, dilated pupils, flushing, and gastrointestinal symptoms.

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

- Things to be careful of

Be careful when engaging in activities requiring mental alertness such as driving a car or operating machinery.

Side Effects

Like all medicines, Polarine Tablet can cause side effects, although not everybody gets them. Tell your doctor or pharmacist if you experience any side effects after taking Polarine Tablet and they worry you, including:

In General: - Urticaria (a red, raised, itchy rash), drug rash, anaphylactic shock (severe, potentially life-threatening allergic reaction), photosensitivity (sensitivity to sunlight) excessive sweating, chills, dryness of the mouth, nose and throat.

Cardiovascular system:- Low blood pressure, headache, an abnormally rapid heart rate, irregular heartbeat and extrasystoles (a heartbeat outside the normal rhythm).

Haematological system:- Abnormal breakdown of red blood cells, low blood platelet count and a decrease in the number of white blood cells

Nervous system:- Sedatives, drowsiness, dizziness, impaired coordination, fatigue, confusion, restlessness, nervousness, excitation, tremors, irritability, insomnia, euphoria, paresthesias (tingling or pricking), blurred vision, double vision, vertigo (dizziness), tinnitus (ringing in the ear), acute labyrinthitis (inflammation of the ear), hysteria, neuritis (inflammation of nerves), epilepsy, central nervous system depression, hallucinations.

Gastrointestinal system: - epigastric pain, anorexia, nausea, vomiting, diarrhoea, constipation.

Urinary system: - frequent urination, difficult urination and urinary retention.

Respiratory system: - thickening of bronchial secretions, tightness of the chest, wheezing, and nasal congestion.

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

You may report any side effect or adverse drug reaction directly to the National Centre for Adverse Drug Reaction Monitoring by calling 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers→Reporting).

Storage and disposal of Polarine Tablet

- Storage

Store at or below 25 ° 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

Oval, deep convex, white, plain tablets without markings.

- Ingredients

- Active Ingredients

- Dexchlorpheniramine Maleate
- Pseudoephedrine Hydrochloride

- Inactive Ingredients

- Aerosil 200
- Lactose
- Maize Starch
- Magnesium stearate

- MAL number

MAL19921008A

Manufacturer

Sunward Pharmaceutical Sdn. Bhd.
No. 9,11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

Product Registration Holder

Sunward Pharmaceutical Sdn. Bhd.
No. 9,11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

Date of revision

02/10/2015

Serial number

BPFK(R4/1)230915/00324