PHARMANIAGA PSEUDOEPHEDRINE T SYRUP

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

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What Pharmaniaga Pseudoephedrine T Syrup is used for

Pseudoephedrine T Syrup is a medicine which is used to relieve the symptoms of colds, flu and allergies including sneezing, runny nose, watery eyes, nasal congestion and blocked sinuses. The syrup contains pseudoephedrine hydrochloride, which is a decongestant that relieves nasal and sinus congestion and triprolidine hydrochloride which is an antihistamine that helps stop sneezing, runny nose and watery eyes.

How Pharmaniaga Pseudoephedrine T Syrup works

Triprolidine works by lowering the level of a naturally-occurring chemical in the body called histamine, which triggers the reaction that leads to allergy symptoms.

Pseudoephedrine works by causing the blood vessels in the sinuses to tighten, decreasing the swelling of the sinuses and making it easier to breathe.

Before you use Pharmaniaga Pseudoephedrine T Syrup

- When you must not use it

Do not take Pharmaniaga Pseudoephedrine T Syrup if you:

- are allergic to any medicine containing pseudoephedrine, triprolidine or any of the ingredients listed below
- have an overactive thyroid gland.
- have glaucoma (increased pressure in the eye)
- have prostate problems (difficulty with passing water or needing to pass water often)
- very high blood pressure or severe heart disease
- are taking, or have taken in the last two weeks, medicines for depression known as Monoamine Oxidase Inhibitors (MAOIs).
- are taking other sympathomimetic medicines (stimulants or appetite suppressants and medicines used to treat congestion and asthma)

-Before you start to use it

Tell your pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor or pharmacist can discuss with you the risks and benefits involved.

Talk to your doctor or pharmacist if you:

- have high blood pressure or heart disease.
- have diabetes or if you been told by your doctor that you have an intolerance to some sugars.
- · are taking alcohol.
- · have epilepsy.

Paediatric use

Use is not recommended in newborn or premature infants and in children under 6 years.

Elderly use

Confusion, dizziness, sedation, low blood pressure, hyperexcitability and anti-cholinergic side-effects, such as dryness of mouth and urinary retention (especially in males) may be more likely to occur in elderly people taking anti-histamines. In addition, elderly people are also more sensitive to the blood vessel contraction and central nervous system effect.

Pregnancy and breastfeeding

Do not take Pharmaniaga Pseudoephedrine T Syrup if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Pharmaniaga Pseudoephedrine T Syrup if you are breast-feeding. Small amount of medicine may be excreted in breast milk. Ask your doctor or pharmacist for advice before taking any medicine.

-Taking other medicines

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

Tell your doctor or pharmacist if you are taking any other medicines, including:

- *Sedatives* (drugs used to treat anxiety and tension).
- Antihypertensives or diuretics (drugs used to treat high blood pressure such as methyldopa, alpha and beta blockers)
- *Tricyclic antidepressants* (used to treat mood disorders).
- Halogenated anaesthetic agents (such as chloroform, cyclopropane, halothane, enflurane or isoflurane).
- Sympathomimetic agent (stimulants or appetite suppressants and drugs used to treat congestion and asthma)

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- Anticholinergics agent such as atropine.
- Monoamine oxidase inhibitors (MAOIs) (used to treat depression).

How to use Pharmaniaga Pseudoephedrine T Syrup

Follow all directions given to you by your pharmacist or doctor carefully. They may differ from the information contained in this leaflet.

If you do not understand the directions on your prescription bottle, ask your pharmacist, nurse, or doctor to explain the instructions to you.

-How much to use

For oral use only.

Always **shake the bottle** thoroughly before use.

Do not use more than the stated dose shown below.

Do not overfill the spoon.

Adults and children over 12 years:

10 mL three or four times a day as needed.

Children:

6-12 years : 5 mL three or four times a day as needed.

4-6 years: 3.75 mL three or four times a day as needed.

2-4 years: 2.5 mL three or four times a day as needed.

Not suitable to be used for children below 2 years of age. Use carefully and follow the advice from doctor or pharmacist for children aged 2 to 6 years.

-When to use it

Leave at least 4 hours between doses.

• Do not give more than 4 doses in 24 hours.

• Use only when simple measures have failed to provide adequate relief.

-How long to use it

Do not use for more than 5 days without consulting your doctor or pharmacist.

This medicine is usually only used for short periods of time. If symptoms persist, consult your doctor.

-If you forget to use it

If you forget to take a dose, take the next dose when needed provided that the last dose was taken at least 4 hours ago.

Do not take a double dose.

-If you use too much (overdose)

Contact your doctor or go to your nearest hospital immediately. Do not drive if you have taken too much. Symptoms of overdoses include:

- Anti-cholinergic effects: Clumsiness or unsteadiness, severe dryness of mouth, nose or throat, flushing or redness of face, shortness of breath or troubled breathing.
- CNS stimulation: Hallucinations, seizures, trouble in sleeping.
- · Severe drowsiness.
- Hypertension (high blood pressure): Continuing headache, slow or fast heartbeat.

While you are using it

-Things you must do

Talk to your pharmacist or doctor if your symptoms do not improve. Your pharmacist or doctor will assess your condition and decide if you should continue to take the medicine.

Elderly people should inform their doctor they are taking this medicine as their doctor may wish to monitor their kidney and liver function.

-Things you must not do

Do not take Pharmaniaga Pseudoephedrine T Syrup to treat any other complaints unless your pharmacist or doctor tells you to.

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

Do not take more than the recommended dose unless your pharmacist or doctor tells you to

-Things to be careful of

This medicine may cause drowsiness. If affected, do not drive or operate machinery.

Avoid alcoholic drink.

Side effects

Tell your pharmacist or doctor if you do not feel well while you are taking Pharmaniaga Pseudoephedrine T Syrup. This medicine helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your pharmacist/doctor to answer any questions you may have.

Get emergency medical help if you have any of these signs of an allergic reaction while taking Pharmaniaga Pseudoephedrine T Syrup: hives; difficult breathing; swelling of your face, lips, tongue, or throat.

Stop using this medication and call your doctor at once if you have a serious side effect such as:

- fast or uneven heart rate;
- mood changes;
- tremor, seizure (convulsions);

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- easy bruising or bleeding, unusual weakness;
- urinating less than usual or not at all·
- feeling short of breath; or
- dangerously high blood pressure (severe headache, blurred vision, buzzing in your ears, anxiety, chest pain, uneven heartbeats, seizure).

Less serious side effects of pseudoephedrine/triprolidine may include:

- dizziness, drowsiness;
- dry mouth, nose, or throat;
- blurred vision; or
- feeling nervous or restless.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects.

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 portal.bpfk.gov.my(Consumers → Reporting)

Storage and Disposal of Pharmaniaga Pseudoephedrine T Syrup

-Storage

Keep the medicines in a cool dry place where the temperature stays below 25°C. Protect from light.

Do not store it or any other medicine in the bathroom, or near a sink, or on a window sill.

Do not leave it in the car on hot days.

Heat and dampness can destroy some medicines.

Do not use this medication after the expiry date which is printed on the product packaging. The expiry date refers to the last day of that month.

Keep it where children cannot reach it.

-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

Clear mixture, yellow in colour with orange flavor.

-Ingredients:

-Active ingredient(s):
Pseudoephedrine T Syrup contains
Pseudoephedrine HCl 30mg/5ml,
Triprolidine HCl 1.25mg/5ml

-Inactive ingredient(s):

Quinoline Yellow, Purified Water, Sugar, Methylparaben, Propylparaben, Orange Sweet and Sodium Saccharin.

-MAL Number

Pharmaniaga Pseudoephedrine T Syrup: MAL20000212A

Manufacturer:

Pharmaniaga Manufacturing Berhad (60016-D),

11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

Product Registration Holder:

Pharmaniaga Manufacturing Berhad (60016-D),

11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

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