

AXCEL TRIDINE SYRUP

Consumer Medication Information Leaflet (RiMUP)

Triprolidine HCl (1.25mg/5ml)

Pseudoephedrine HCl (30mg/5ml)

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WHAT AXCEL TRIDINE SYRUP IS USED FOR

Axcel Tridine Syrup is used for the relief of nasal and respiratory congestion, common cold, acute sinusitis (inflammation of the sinuses), allergic rhinitis (inflammation of the mucous membrane inside the nose) and vasomotor rhinitis (non-allergic rhinitis).

HOW AXCEL TRIDINE SYRUP WORKS

Pseudoephedrine hydrochloride is a direct and indirect acting sympathomimetic agent and is an effective upper respiratory tract decongestant. It is combined with Triprolidine hydrochloride in preparations intended for the relief of cough and cold symptom.

Triprolidine hydrochloride is a histamine H1-receptor antagonist. It works by preventing the actions of histamine. Histamine is a substance produced by the body as part of its defence mechanisms. It causes the symptoms of allergic reactions. Triprolidine hydrochloride blocks histamine from binding to its receptors in various parts of the body and this stops it causing the symptoms of an allergic reaction.

BEFORE YOU USE AXCEL TRIDINE SYRUP

When you must not use it

Do not take Axcel Tridine Syrup if:

- If you are allergic or hypersensitive to antihistamines, propylene glycol and pseudoephedrine.
- If you have severe hypertension (high blood pressure) or severe coronary artery (heart) disease.
- If you take any monoamine oxidase inhibitor (MAOI) drugs.
- If it is not prescribed by a qualified doctor or pharmacist for you.
- Do not take Axcel Tridine Syrup if you are pregnant, trying to get pregnant or think you may be pregnant.
- Do not take Axcel Tridine Syrup if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Before you start to use it

Tell your doctor:

- If you are allergic to any medicines, food and dyes.
- If you are taking any other medicines including those not prescribed by your doctor.
- If you have narrow angle glaucoma (a buildup of pressure in the eye that affects vision).
- If you suffer from diabetes mellitus.
- If you suffer from urinary retention.
- If you have a history of bronchial asthma.
- If you have hyperthyroidism (a raised level of thyroid hormone).
- If you experienced epilepsy.
- If you experienced cardiovascular (heart) disease.
- If you experienced prostatic enlargement.
- If you experienced severe kidney and liver impairment.
- Pregnancy and breastfeeding.

Taking other medicines

You should tell your doctor if you are taking the following medicine as it may interact with your Axcel Tridine Syrup:

- Central nervous system (CNS) depressants including alcohol, narcotic analgesics, sedatives and tranquillisers.
- Monoamine oxidase inhibitors (MAOIs), antihypertensive, cardiac glycosides, furozolidine, sympatholytics, quinidine or tricyclic antidepressants.
- Aminoglycoside antibiotics.

HOW TO USE AXCEL TRIDINE SYRUP

How much to use

To be taken orally, 3 times daily.

Children:

2-5 years: 2.5ml

6-12 years: 5ml

Adult and children above 12 years:
10ml

When to use it

Your doctor will decide when it is appropriate for you to take Axcel Tridine Syrup according to the type of infection you have.

How long to use it

Continue taking Axcel Tridine Syrup for as long as 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 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)

Symptoms of overdose:

- In children, ataxia (uncoordinated movement) may occur.
- Tremor
- Psychose (abnormal condition of the mind)
- Hallucination
- Convulsion
- Hyperpyrexia (elevation of body temperature)

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- Hypotension (low blood pressure)

You must inform your doctor immediately if you have taken too much Axcel Tridine Syrup.

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 Axcel Tridine Syrup.
- Tell your doctor immediately if you become pregnant while talking 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 Axcel Tridine Syrup to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

- Avoid driving or operating machine as Axcel Tridine Syrup may cause drowsiness.
- Pregnancy and lactation.
- Not recommended for newborn and premature infants.

SIDE EFFECTS

Like all medicines, Axcel Tridine Syrup can cause side effects although not everybody gets them. You are advised to consult doctor/pharmacist for further information. The following side effects have been reported:

- Sedation including inability to concentrate, lassitude (weakness), dizziness, hypotension, muscular weakness and incoordination.
- Gastrointestinal disturbances such as nausea, vomiting, diarrhoea or constipation, colic and epigastric pain.
- Headache.
- Blurred vision.

- Tinnitus (ringing in the ear).
- Elation or depression.
- Irritability.
- Anxiety.
- Tachycardia (a faster than normal heart rate).
- Palpitations.
- Tremor.
- Insomnia.
- Confusion.
- Anorexia.
- Difficulty in urination.
- Urinary retention.
- Dyspnoea (breathing difficulty).
- Dryness of the mouth.
- Tightness of chest.

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 AXCEL TRIDINE SYRUP

Storage

Keep Axcel Tridine Syrup out of reach children. Keep container well closed. Store below 30°C. Protect from light.

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

How it looks like

Axcel Tridine Syrup is cherry red in colour syrup with fruity flavour.

Ingredients

Active Ingredients:

Pseudoephedrine Hydrochloride,
Tripolidine Hydrochloride.

Inactive Ingredients:

Refined Sugar, Methylparaben USP, Glycerin, Cherry Red, Propylene Glycol, Mix Fruit Flavour, Sodium Saccharin, Purified Water.

MAL Number

MAL20012739A

MANUFACTURER AND PRODUCT REGISTRATION HOLDER

KOTRA PHARMA (M) SDN BHD
No. 1, 2 & 3, Jalan TTC 12,
Cheng Industrial Estate,
75250 Melaka, Malaysia.

DATE OF REVISION

04/12/2014

SERIAL NUMBER

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