

AXCEL NASATAB TABLET

Paracetamol / Chlorpheniramine Maleate / Pseudoephedrine HCl (500mg /4mg /60mg)

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WHAT AXCEL NASATAB TABLET IS USED FOR

Axcel Nasatab Tablet is used for symptomatic relief of:

- Headache.
- Fever and pain.
- Sinus and nasal congestion associated with sinusitis (inflammation of the sinuses) or common cold.

HOW AXCEL NASATAB TABLET WORKS

Paracetamol consists of analgesic-antipyretic (an agent that relieves pain and reduces fever) effect. Chlorpheniramine maleate acts as antihistamine and contains anticholinergic effects. It works by blocking a certain natural substance (histamine) that your body makes during an allergic reaction. Pseudoephedrine is a decongestant (medicine that reduces nasal blockage caused by an infection or allergy). It is a direct and indirect-acting sympathomimetic agent that provides vasoconstriction (constriction of the blood vessels).

BEFORE YOU USE AXCEL NASATAB TABLET

When you must not use it

Do not take Axcel Nasatab Tablet if:

- If you are having hypersensitivity to any of its active ingredients in the product.
- If you are having severe hypertension (high blood

pressure) or severe coronary artery disease (heart disease).

- If you are taking Monoamine oxidase inhibitors (MAOI), or within 14 days of taking them.
- If it is not prescribed by a qualified doctor or pharmacist for you.
- Do not take Axcel Nasatab Tablets if you are pregnant, trying to get pregnant or think you may be pregnant.
- Do not take Axcel Nasatab Tablets 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:

- If you are allergic to any medicines, food and dyes.
- If you are having narrow angle glaucoma (buildup of pressure in the eye), history of bronchial asthma, hyperthyroidism (a raised level of thyroid hormone), cardiovascular (heart / blood vessels) disease, prostatic hypertrophy (enlargement of the prostate), high blood pressure or diabetes mellitus.
- If you are having impaired kidney or liver function or taking other drugs that affect the liver.
- If you are taking any other medicines (including those not prescribed by your doctor).
- 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 Nasatab Tablet:

- Metoclopramide.
- Central Nervous System (CNS) depressants including alcohol, barbiturates, hypnotics, opioid analgesics and anxiolytic.
- Methyldopa, mecamylamine, reserpine and veratrum alkaloids.
- Beta-adrenergic-blocking agents.
- Digitalis (for heart disorders)
- Antacids and kaolin.

- Paracetamol containing medicines.

HOW TO USE AXCEL NASATAB TABLET

How much to use

For Adults only:

1 tablet to be taken 3 or 4 times daily.

When to use it

Your doctor will decide when it is appropriate for you to use Axcel Nasatab Tablet according to the type of condition you have.

How long to use it

Continue taking Axcel Nasatab Tablet 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 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)

- Dizziness, tinnitus (ringing in the ears), ataxia (uncoordinated movement), blurred vision, dry mouth, flushing and gastrointestinal symptoms.
- Acute hypertension (high blood pressure) or cardiovascular collapse with accompanying hypotension (low blood pressure) may occur.
- Within 24 hours of overdosage, nausea, vomiting, lethargy and sweating may occur.
- Treatment is symptomatic and supportive.

It is advisable for you to contact and inform your doctor if you did take Axcel Nasatab Tablet too much.

WHILE YOU ARE USING IT

Things you must do

- Take your medicine exactly as your doctor has told you.

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- Tell all the doctors, dentists and pharmacists treating you that you are taking Axcel Nasatab Tablets.
- 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 Nasatab Tablets to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

- Patients should be warned against activity required mental alertness such as driving and operating machinery.
- Pregnancy and breastfeeding.

SIDE EFFECTS

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

Due to preparation contains antihistamine:

- Sedation.
- Lassitude (weakness).
- Dizziness.
- Hypotension (low blood pressure).
- Muscular weakness.
- Inco-ordination.
- Gastro-intestinal disturbances.
- Headache.
- Blurred vision.
- Tinnitus (ringing in the ears).
- Elation or depression.
- Irritability.
- Anorexia (eating disorder).
- Difficulty in urination.
- Dryness of the mouth.
- Tightness of the chest.
- Heaviness.
- Weakness of the hands.

Due to paracetamol:

- Epigastric distress or skin rash.

Due to sympathomimetics agents:

- Fear.
- Anxiety.
- Restlessness.
- Tremor.
- Insomnia.
- Confusion.
- Irritability.
- Psychotic states

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 NASATAB TABLET

Storage

Keep Axcel Nasatab Tablet out of reach of children.

Store below 30°C. Keep container well closed and protect from light.

Disposal

Do not use Axcel Nasatab Tablet after the expiry date which is stated on the carton.

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

Axcel Nasatab Tablet is yellow, round flat tablet marked with KOTRA logo one side, 12.9mm in diameter.

Ingredients

Active Ingredients:

Paracetamol, Chlorpheniramine Maleate and Pseudoephedrine HCL.

Inactive Ingredients:

Quinoline Yellow, Sodium Starch Glycolate, PVP K90, PVP K30, Aerosil 200, Microcrystalline

Cellulose, Magnesium Stearate and Purified water.

MAL Number

MAL20021133A

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

16/06/2015

SERIAL NUMBER

BPFK(R4/1)080515/00099