AXCEL NASATAB SUSPENSION

Chlorpheniramine maleate / Pseudoephedrine hydrochloride / Paracetamol (2mg/30mg/250mg per 5ml)

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What Axcel Nasatab Suspension is used for

Axcel Nasatab Suspension consists of a combination of three medicines; paracetamol, chlorpheniramine maleate, and pseudoephedrine hydrochloride. It is used for symptomatic relief of:

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

How Axcel Nasatab Suspension works

Paracetamol has analgesicantipyretic effect. It works by stopping the pain message from getting through the brain and reducing fever.

Chlorpheniramine maleate acts as an antihistamine that reduces allergic symptoms by blocking a certain natural substance (histamine) that your body makes during an allergic reaction.

Pseudoephedrine hydrochloride is a decongestant. It works by causing narrowing of the blood vessels in the nasal passages to to improve air circulation and reduces nasal congestion.

Before you use Axcel Nasatab Suspension

When you must not use it

Do not take Axcel Nasatab Suspension if:

- You have hypersensitivity to any of its active ingredients in the product.
- You have severe high blood pressure or severe coronary artery disease (heart disease).
- You are taking MAOI (monoamine oxidase inhibitor) for depression, or within 14 days of taking them.
- It is not prescribed by a qualified doctor or pharmacist for you.
- Pregnancy and breastfeeding
 Ask your doctor for advice
 before taking any medicine. It
 should only be used during
 pregnancy or breastfeeding after
 their potential benefits have been
 weighed against the risks.

Axcel Nasatab Suspension should not be used in children less than 2 years of age. Use with caution and doctor's advice in children 2 to 6 years of age.

This preparation contains Paracetamol. Do not take any other Paracetamol containing medicines at the same time. Paracetamol overdose may harm the liver. Follow the recommended dose.

Before you start to use it

Tell your doctor if:

- You are allergic to any medicines, food and dyes.
- You have narrow angle glaucoma (increased pressure inside the eye), history of bronchial asthma, cardiovascular (heart and blood vessel) disease, overactive thyroid, diabetes, high blood pressure, enlargement pyloroduodenal prostate, obstruction (gastric outflow obstruction) or bladder neck obstruction.
- You have impaired kidney or liver function or taking other medicines that affect the liver.

Taking other medicines

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

- Oral anticoagulant (prevent blood clots)
- Metoclopramide.
- Probenedic.
- Central nervous system depressants including alcohol, barbiturates, hypnotics, opioid analgesics and anxiolytic.
- Colestyramine.
- MAOI (monoamine oxidase inhibitors).
- Guanenthidine for high blood pressure.
- Paracetamol containing medicines.

How to use Axcel Nasatab Suspension

How much to use

- For adults and children above 12 years old: 10 ml suspension to be taken 3 or 4 times daily.
- For children within the age of 6-12 years old: 5ml suspension to be taken 3 to 4 times daily.
- For children within the age of 2-5 years old: 2.5ml suspension to be taken 3 to 4 times daily.

When to use it

Your doctor will decide when it is appropriate for you to take Axcel Nasatab Suspension.

How long to use it

- Take this medicine as stated in the leaflet without exceeding the dosage.
- Follow any recommendations and advices from your doctor or pharmacist.

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.

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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.

Symptoms of overdosage may include

 dizziness, tinnitus (ringing in the ears), ataxia (lack of voluntary coordination of muscle movements), blurred vision, dry mouth, flushing, gastro-intestinal symptoms and convulsions.

Symptoms that may occur within 24 hours of overdosage of Paracetamol include nausea, vomiting, lethargy, and sweating. Abdominal pain may be the first indication of liver damage. Liver failure, encephalopathy (brain disorder), coma, and death may result.

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 Nasatab Suspensions.
- Tell your doctor immediately if you become pregnant while talking this medication.

Things you must not do

- Do not take this medicine more than the suggested dosage in a day.
- Do not take any new medicines without consulting your doctor.
- Do not give Axcel Nasatab Suspensions to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

- This preparation may cause drowsiness and dulling of mental alertness. Be careful when driving or operating machinery.
- Avoid consuming alcohol.

Side effects

Like all medicines, Axcel Nasatab Suspension 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 antihistamine:

- Sedation.
- Lassitude.
- Dizziness.
- Low blood pressure.
- Muscular weakness.
- Inco-ordination.
- Gastro-intestinal disturbances.
- Headache.
- Blurred vision.
- Tinnitus (ringing in the ears).
- Elation or depression.
- Irritability.
- Anorexia.
- Difficulity in urination.
- Dryness of the mouth.
- Tightness of the chest.
- Heaviness and weakness of the hands.
- Epigastric distress or skin rash.

Due to sympathomimetics agents (pseudoephedrine):

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

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 Suspension

<u>Storage</u>

Keep Axcel Nasatab Suspension out of reach of children.

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

Disposal

Do not use Axcel Nasatab Suspension 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 Suspension is yellow to brownish coloured liquid with mango flavor.

Ingredients

Active Ingredients:

Paracetamol, Chlorpheniramine Maleate and Pseudoephedrine HCL.

Inactive Ingredients:

Quinoline Yellow, Sodium Citrate Dihydrate, Citric Acid Anhydrous, Methylparaben, Propylene Glycol Saccharin Sodium, Purified Water, Refined Sugar, Mango Flavour, and Xanthan Gum.

MAL Number

MAL20112113A

Manufacturer and product registration holder

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

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