

AXCEL KETOTIFEN SYRUP

Consumer Medication Information Leaflet (RiMUP)

Ketotifen Hydrogen Fumarate (1mg/5ml)

What is in this leaflet

1. What Axcel Ketotifen Syrup is used for
2. How Axcel Ketotifen Syrup works
3. Before you use Axcel Ketotifen Syrup
4. How to use Axcel Ketotifen Syrup
5. While you are using it.
6. Side effects
7. Storage and Disposal of Axcel Ketotifen Syrup
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Axcel Ketotifen Syrup is used for

Axcel Ketotifen Syrup is for long-term prevention of bronchial asthma, allergic bronchitis (swelling and inflammation of the main air passages to the lungs), asthmatic symptoms associated with hay fever. It is also use for prevention and treatment of multisystem allergies, allergic rhinitis (inflammation of the nasal airways), allergic skin reactions and allergic conjunctivitis (swelling or infection of the membrane lining the eyelids).

How Axcel Ketotifen Syrup works

Ketotifen is a nonbronchodilator (do not relax the bronchial muscles), anti-asthmatic drug with marked antianaphylactic properties (the state of desensitization to antigens) and a specific antihistaminic effect.

Before you use Axcel Ketotifen Syrup

- When you must not use it
Do not take Axcel Ketotifen Syrup if:
 - If you are allergic or hypersensitive to any other ingredients in this syrup.
 - Do not take Axcel Ketotifen Syrup if you are pregnant, trying to get pregnant or think you may be pregnant.

- Do not take Axcel Ketotifen 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:

- If you are allergic to any medicines, food and dyes.
- If you are taking any other medicines (including those not prescribed by your doctor).

- Taking other medicines

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

- Oral antidiabetic agents

How to use Axcel Ketotifen Syrup

- How much to use

To be administered orally. 5ml twice daily with morning and evening meals.

In patients susceptible to sedation, a progressive regimen is recommended during the first week of treatment commencing with 2.5-5ml at night and increasing to full therapeutic doses.

If necessary, the dosage may be increased up to 20ml a day in divided doses.

Children:

6 months-3 years: 2.5ml twice daily.

Above 3 years: 5ml twice daily.

- When to use it

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

- How long to use it

Continue taking Axcel Ketotifen Syrup for as long as your 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)

- Drowsiness to severe sedation, confusion and disorientation, tachycardia (fast or irregular heartbeat rate) and hypertension (high blood pressure), especially in children, hyperexcitability or convulsions, reversible coma.

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

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 Ketotifen Syrup.
- 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 Axcel Ketotifen Syrup to anyone else, even if they have the same symptoms or condition as you.

AXCEL KETOTIFEN SYRUP

Consumer Medication Information Leaflet (RiMUP)

Ketotifen Hydrogen Fumarate (1mg/5ml)

- Things to be careful of

- Pregnancy and lactation.
- During the first few days of treatment, your reaction may be impaired and you should therefore exercise care when doing activity that requires full alert.

Side effects

Like all medicines, Axcel Ketotifen 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.
- Weight gain.
- Symptoms of central nervous system (CNS) stimulation.

- Rare side effects:

- Dry mouth.
- Slight dizziness.

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 Ketotifen Syrup

- Storage

Keep Axcel Ketotifen Syrup out of reach of children.

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

- Disposal

Do not use Axcel Ketotifen Syrup 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 Ketotifen Syrup is orange coloured syrup with orange flavour.

- Ingredients

Active Ingredient (s):

Ketotifen Hydrogen Fumarate

Inactive Ingredients:

Orange Flavour, Purified Water, Carboxymethylcellulose Sodium, Sunset Yellow Dye, Propylene Glycol, Sodium Benzoate and Refined Sugar.

- MAL Number

MAL19971379A

Manufacturer

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

Product Registration Holder

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

Date of revision

21/08/2014