

# AXCEL LORATADINE SYRUP

Loratadine (5mg/5ml)

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## WHAT AXCEL LORATADINE SYRUP IS USED FOR

Axcel Loratadine Syrup is used for the relief of symptoms associated with allergic rhinitis (inflammation of the mucous membrane inside the nose) for example sneezing, nasal discharge (rhinorrhea) and itching, as well as ocular (eye) itching burning, chronic urticaria (a raised, itchy rash on the skin) and other allergic dermatologic (skin) disorders.

## HOW AXCEL LORATADINE SYRUP WORKS

Loratadine is a long-acting tricyclic antihistamine with selective peripheral histamine H<sub>1</sub>-receptor antagonist activity. It works by blocking the action of one of the body's natural chemicals known as histamine. Histamine is responsible for many of the symptoms caused by allergies.

## BEFORE YOU USE AXCEL LORATADINE SYRUP

### When you must not use it

Do not take Axcel Loratadine Syrup if:

- If you are allergic or hypersensitive to any ingredients in Axcel Loratadine Syrup.
- If it is not prescribed by a qualified doctor or pharmacist for you.
- Do not take Axcel Loratadine Syrup if you are pregnant, trying

to get pregnant or think you may be pregnant.

- Do not take Axcel Loratadine Syrup if you are breast-feeding. Loratadine is excreted in breast milk. Ask your doctor or pharmacist for advice before taking any medicine.

### Before you start to use it

Tell your doctor if you:

- 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 severe liver impairment.

Use in children:

Safety and efficacy of loratadine in children below 2 years old have not been established.

### Taking other medicines

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

- Alcohol.
- Ketoconazole (antifungal).
- Erythromycin (antibiotic).
- Cimetidine (medicine to treat ulcer of the stomach).
- Amprenavir (medicine to treat HIV infection).

## HOW TO USE AXCEL LORATADINE SYRUP

### How much to use

To be taken orally and only once a day.

Children (2-12 years):

Weight greater than 30kg: 10ml daily.

Weight lighter than 30 kg: 5ml daily

Adults and children above 12 years: 10ml daily.

Liver impairment:

Initial dose of 5ml once daily or 10ml every other day.

### When to use it

Your doctor will decide when it is appropriate for you to take Axcel Loratadine Syrup.

### How long to use it

Continue taking Axcel Loratadine 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)

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.

## 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 Loratadine 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 Loratadine Syrup to anyone else, even if they have the same symptoms or condition as you.

### Things to be careful of

- Caution for patients with severe liver impairment to administer a

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lower initial dose because they may have reduced clearance of loratadine

- Pregnancy and breastfeeding.
- Children < 2 years old.

## SIDE EFFECTS

Like all medicines, Axcel Loratadine 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 rarely:

- Headache
- Sedation
- Nervousness

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](http://portal.bpfk.gov.my) (Consumers -> Reporting).

## STORAGE AND DISPOSAL OF AXCEL LORATADINE SYRUP

### Storage

Keep Axcel Loratadine 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 Loratadine Syrup is colourless syrup with peach flavour.

### Ingredients

#### *Active Ingredient:*

Loratadine

#### *Inactive Ingredients:*

Refined Sugar, Sodium Benzoate, Citric Acid, Sodium Saccharin, Sorbitol, Propylene Glycol, Peach Flavour, Purified Water, Aspartame.

### MAL Number

MAL20021421AZ

### 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

22/05/2015

### SERIAL NUMBER

BPFK(R4/1)190515/00111