

# AXCEL LORATADINE TABLET

Consumer Medication Information Leaflet (RiMUP)

Loratadine (10mg)

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## WHAT AXCEL LORATADINE TABLET IS USED FOR

Axcel Loratadine Tablet is used to relief 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 and burning, chronic urticaria (a raised, itchy rash that appears on the skin) and other allergic dermatologic disorders.

## BEFORE YOU USE AXCEL LORATADINE TABLET

### When you must not use it

Do not take Axcel Loratadine Tablet if:

- If you are allergic or hypersensitive to Loratadine.
- It is not prescribed by a qualified doctor or pharmacist for you.
- Do not take Axcel Loratadine Tablet if you are pregnant, trying to get pregnant or think you may be pregnant.
- Do not take Axcel Loratadine Tablet 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.
- If you are having severe liver impairment
- If you are pregnant and breastfeeding.

### Taking other medicines

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

- Ketoconazole.
- Erythromycin.
- Cimetidine.
- Amprenavir.
- Alcohol.

## HOW TO USE AXCEL LORATADINE TABLET

### How much to use

For oral administration only. Once a day.

Adult and children >12 years: 1 tablet daily.

Children 2-12 years and >30 kg: 1 tablet daily; <30kg: ½ tablet daily.

Use in children:

Safety and efficacy of loratadine in children < 2 years have not yet been established.

### When to use it

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

### How long to use it

Continue taking Axcel Loratadine 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)

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.

You must inform your doctor immediately if you have taken too much Axcel Loratadine Tablet.

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

### Things to be careful of

- Avoid prolonged use with high dosage.
- Caution is needed while applying on children < 2 years.

## SIDE EFFECTS

Like all medicines, Axcel Loratadine Tablet 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:

- Headache.
- Sedation.
- Nervousness.

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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).

Cheng Industrial Estate,  
75250 Melaka, Malaysia.

#### DATE OF REVISION

18/12/2014

#### SERIAL NUMBER

BPFK(R4/1)091214/00077

#### STORAGE AND DISPOSAL OF AXCEL LORATADINE TABLET

##### Storage

Keep Axcel Loratadine Tablet out of reach of children.

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

##### Disposal

Do not use Axcel Loratadine 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 Loratadine Tablet is a white to off white coloured, round, flat face beveled edge tablet with a single score line on one side and marked KOTRA logo on the other sides, 7.1mm diameter.

##### Ingredients

###### *Active Ingredient:*

Loratadine

###### *Inactive Ingredients:*

Magnesium Stearate, Lactose Monohydrate, Sodium Starch Glycolate, and Microcrystalline Cellulose PH102.

##### MAL Number

MAL20031927A

#### MANUFACTURER AND PRODUCT REGISTRATION HOLDER

KOTRA PHARMA (M) SDN BHD  
No. 1, 2 & 3, Jalan TTC 12,