# **ZORATADINE SYRUP**

Loratadine (5mg/5ml)

#### What is in this leaflet

- 1. What ZORATADINE SYRUP is used for
- 2. How ZORATADINE SYRUP works
- 3. Before you take ZORATADINE SYRUP
- 4. How to take ZORATADINE SYRUP
- 5. While you are taking ZORATADINE SYRUP
- 6. Side effects
- 7. Storage and Disposal of ZORATADINE SYRUP
- 8. Product description
- 9. Product Registration Holder and Manufacturer
- 10. Date of revision

This leaflet answers some common questions about. It does not contain all the information that is known about ZORATADINE SYRUP.

It does not take the place of talking to your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

## What ZORATADINE SYRUP is used for

ZORATADINE **SYRUP** indicated for the relief of symptoms associated with allergic rhinitis (inflammation of the mucous membrane inside the nose), such as discharge sneezing, nasal (rhinorrhea) and itching, as well ocular (eve) itching and burning. It is also indicated for relief of symptoms and signs of chronic urticaria (a red, raised, itchy rash) and other allergic dermatological (skin) disorders.

### How ZORATADINE SYRUP works

ZORATADINE SYRUP contains Loratadine as active ingredient.

**Loratadine** belongs to a group of medicines called antihistamines, it works by blocking the action of histamine, a substance in the body that causes allergic symptoms.

Ask your pharmacist or doctor if you have any questions about this medicine.

# Before you take ZORATADINE SYRUP

- When you must not take it

Do not take ZORATADINE SYRUP if:

• You are allergic (hypersensitive) to loratadine or any other ingredients in the medicine

#### - Before you start to take it

Tell your doctor if you have or have had any of the following medical conditions:

• Liver problems

Pregnancy and breast feeding: Talk to you doctor before taking this medicine if you are pregnant, might become pregnant or are breast-feeding.

Loratadine is excreted into breast milk and due to the increased risk of antihistamine for infants, particularly newborns and premature infants, a decision should be made whether to discontinue nursing or discontinue the medicine.

#### - Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Medicines which affect the liver should be used with caution.

### How to take ZORATADINE SYRUP

#### - How much to take

Adult and Children 12 years of age and over — Two 5ml spoonfuls (10mg) once daily.

Children 2 to 12 years of age: Body weight > 30kg - Two 5ml spoonfuls (10mg) syrup once daily.

Body weight  $\leq 30 \text{kg} - \text{One 5ml}$  spoonful (5mg) syrup once daily.

#### - When to take it

Use as directed by your doctor or pharmacist.

### - How long to take it

Depends on every individual. Consult your doctor for the exact duration of this medicine.

### - If you forget to take it

Take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the medicine at your next regularly scheduled time.

Do not try to make up for missed doses by taking more than one dose at a time.

### - If you take too much (overdose)

Reported symptoms of overdosage are;

- Somnolence (drowsiness/ sleepiness)
- Tachycardia (an abnormally rapid heart rate)
- Headache

Immediately telephone your doctor for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much ZORATADINE SYRUP.

## While you are taking ZORATADINE SYRUP

### - Things you must do

Tell your doctor immediately if you become pregnant while taking this medication.

If you are about to start taking on any other new medicine, tell your pharmacist or doctor that you are taking ZORATADINE SYRUP.

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

### - Things to be careful of

Do not take charge of vehicles or machinery until the effect of ZORATADINE SYRUP treatment on the individual is known.

#### Side effects

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ZORATADINE SYRUP against the benefits they expect it will have for you.

Like all medicines, ZORATADINE SYRUP can cause side effects, although not everybody gets them.

Possible side effects are;

- Fatigue
- Headache
- Sleepiness
- Dry mouth
- Gastrointestinal disorders such as nausea, gastritis (stomach inflammation)
- Allergic symptoms like rash

If you get any side effects, even those not mentioned in this leaflet, 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 ZORATADINE SYRUP

#### - <u>Storage</u>

Keep container well-closed. Store below 30°C. Keep in a cool dry place, protected from strong light. Keep out of reach of children.

#### - <u>Disposal</u>

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

ZORATADINE SYRUP is a clear slightly viscous liquid, pale-straw in colour with cherry flavour.

#### - Ingredients

Active ingredient:

Each 5ml contains loratadine 5mg.

### Inactive ingredients:

Sodium Benzoate, Propylene Glycol, Sucrose, Citric Acid, Sodium Citrate, Cherry Flavor, Disodium Edetate, and Purified Water.

### - <u>MAL number</u> MAL10053669AZ

# Product Registration Holder and Manufacturer

HOE Pharmaceuticals Sdn Bhd Lot 10, Jalan Sultan Mohamed 6, Bandar Sultan Suleiman, 42000 Port Klang, Selangor, MALAYSIA.

**Date of revision** 21/09/2015

**Serial number** BPFK(R4/1)240815/00277