

ZORATADINE-P SYRUP

Loratadine/Pseudoephedrine Sulfate (5mg/60mg per 5ml)

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This leaflet answers some common questions about Zoratadine-P Syrup. It does not contain all the information that is known about Zoratadine-P 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-P Syrup is used for

Zoratadine-P Syrup is indicated for the relief of symptoms associated with allergies rhinitis (inflammation of the mucous membrane inside the nose) and the common cold including nose congestion, sneezing, running nose, itchiness and watery eyes.

How Zoratadine-P Syrup works

Zoratadine-P Syrup contains loratadine and pseudoephedrine sulfate as active ingredients.

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.

Pseudoephedrine sulfate is a decongestant that shrinks blood vessels in the nasal passages. This

leads to clearing of the stuffy or blocked nose.

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

Before you use Zoratadine-P Syrup

When you must not use it

Do not take Zoratadine-P Syrup if:

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

Before you start to use it

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

- increased intraocular (inside the eye) pressure
- difficulty to empty the bladder
- prostatic hypertrophy (enlargement of prostate)
- severe high blood pressure
- chronic heart disease
- hyperthyroidism (overactive thyroid gland)
- on treatment with monoamine oxidase inhibitor (MAOI) or within 14 days of discontinuing such treatment
- narrowing of gastric passage due to a lesion in the lining of the stomach (stenosing peptic ulcer)
- Blockage in between pylorus and duodenum (part of stomach)
- liver impairment
- diabetes mellitus

Pregnancy and breast feeding:

- Talk to your doctor before taking this medicine if you are pregnant, might become pregnant, plan to get pregnant or are breast-feeding.
- Safe use of Zoratadine-P Syrup during pregnancy has not been established.

- Loratadine and pseudoephedrine sulfate are excreted in breast milk, thus decision has to be made whether to stop breast feeding or stop using Zoratadine-P Syrup.

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.

These include:

- ketoconazole (antifungal)
- erythromycin (antibiotic)
- cimetidine (to treat gastric ulcer)
- monoamine oxidase inhibitors (MAOIs) for depression
- methyl dopa, mecamylamine, reserpine, veratum alkaloids (for high blood pressure)
- digitalis (to treat heart disorder)
- antacid (to treat stomach acidity)
- kaolin (for diarrhoea)

How to use Zoratadine-P Syrup

How much to use

To be taken by mouth.

Adult and Children 6-12 years (>30kg body weight): 5mL twice daily

Children 6-12 years (≤30kg body weight): 2.5mL twice a day

Safety and efficacy of Zoratadine-P Syrup in children below 6 years have not been established.

When to use it

Use as directed by your doctor or pharmacist.

How long to use it

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

If you forget to use 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 use too much (overdose)

Taking too much Zoratadine-P Syrup may cause sedation, apnea (pauses in breathing while you are sleeping), insomnia, hallucination, euphoria, excitement, tachycardia (an abnormally rapid heart rate), thirst, perspiration, high or low blood pressure, giddiness, headache, nausea, vomiting or difficulty in urination.

This is not a complete list of overdose symptoms. Contact your doctor or pharmacist if you experience any other symptoms.

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-P Syrup.

While you are using Zoratadine-P Syrup

Things you must do

If you are about to start taking on any other new medicine, tell your pharmacist or doctor that you are taking Zoratadine-P Syrup.

Tell all the doctors, dentists and pharmacists treating you that you are taking Zoratadine-P Syrup.

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

Things you must not do

Do not share this medicine with anyone else, even if they appear to have the same condition as you.

Do not take any new medicines without consulting your doctor.

Things to be careful of

Antihistamines should be discontinued approximately 48 hours before skin testing procedures.

Do not take charge of vehicles or machinery until the effect of Zoratadine-P Syrup treatment on the individual is known.

Elderly aged 60 years and above are more likely to experience adverse reactions such as confusions, hallucinations, central nervous system (CNS) depressions and death.

Side effects

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Zoratadine-P Syrup against the benefits they expect it will have for you.

Like all medicines, Zoratadine-P Syrup can cause side effects, although not everybody gets them. Possible side effects are headache, nervousness, dizziness, tiredness, nausea, confusions, dry mouth, and trouble sleeping (insomnia).

This is not a complete list of side effects. 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-P Syrup

Storage

Store below 30°C.

Keep in a cool dry place, protected from strong light.
Keep out of reach of children.

Disposal

Dispose the medicine after the expiry date.

Medicines should not be disposed of via wastewater or household waste.

Consult your pharmacist on how to safely dispose of any medicines that are no longer required.

Product description

What it looks like

A clear slight viscous liquid, yellow in colour with rootbeer flavour.

Ingredients

Active ingredients:

Each 5ml contains Loratadine 5mg and Pseudoephedrine sulfate 60mg.

Inactive ingredients:

Sucralose, Rootbeer Flavour 4184, Sucrose, Sodium Benzoate, Citric acid anhydrous, Sorbitol 70%, Propylene Glycol, Glycerin, and Purified Water.

MAL number

MAL10053674A

Manufacturer and Product Registration Holder

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