

Item Code	: Draft 23 Apr 2026
PM Code	: L.P. LDS 4L
Measurement(mm) ± 2mm	: 237(L) x 135(H)
Colour of Artwork	: P. 376 C K
Source of Artwork	: MAC 2 / CC

Contraindications:

Loratadine products are contraindicated in patients who have shown hypersensitivity or idiosyncrasy to their component.

Side Effects / Adverse Reactions:

The incidence of adverse effects associated with loratadine syrup has been comparable to that of placebo. In controlled pediatric clinical trials, the incidence of treatment-related headache sedation and nervousness, which were rarely reported events, was similar to that in placebo.

Drug Interaction:

- When administered concomitantly with alcohol, loratadine has no potentiate effects as measured by psychomotor performance studies.
- Ketoconazole, erythromycin, and cimetidine may increase plasma-loratadine concentration, but without clinically significant changes (including electrocardiographic).
- Plasma concentration of loratadine possibly increased by amprenavir.
- Other drugs known to inhibit hepatic metabolism should be co-administered with caution until definitive interaction studies can be completed.

Symptoms and Treatment for Overdosage and Antidotes:

To date overdosage has not occurred with loratadine. A single acute ingestion of 160mg produced no adverse effects. In the event of overdosage, treatment, which should be started immediately, is symptomatic and supportive. Treatments include gastric lavage and/or activated charcoal, induction of emesis with ipecac syrup, close observation and general supportive measures. Loratadine is not cleared by hemodialysis to any appreciable extent. After an emergency, the patient should continue to be medically monitored.

Shelf-life:

3 years from the date of manufacture.

KEEP IN A TIGHT CONTAINER.
STORE AT TEMPERATURE BELOW 30°C.
PROTECT FROM LIGHT AND MOISTURE.
KEEP MEDICINE OUT OF REACH OF CHILDREN.
JAUHKAN DARIPADA KANAK-KANAK.



Scan QR code to
access package insert

BARCODE

Batch No.:

Mfg. Date:

Exp. Date:

xxxxx printing code xxxxx

Loratadine[®]
syrup 1mg/ml

4L

Antihistamine, Agent

For allergy symptoms such as:

- Sneezing
- Runny nose
- Watery & Itchy eyes

Peach Flavour

Alcohol Free

Product description and Packing(s):

Colorless to slight-yellow liquid with fruit flavored odor.
Plastic bottle of 30mL, 60mL, 100mL, 120mL and 4L.

Ingredients:

Each millilitre contains:

Loratadine 1mg

Preservative:

Sodium Benzoate 0.6mg/ml

Manufacturer & Product Registration Holder

Y.S.P. INDUSTRIES (M) SDN. BHD. (199001001034)

Lot 3, 5, 7, 12 & 14, Jalan P/7, Section 13,

Kawasan Perindustrian Bandar Baru Bangi,

43000 Kajang, Selangor, Malaysia.

A Subsidiary of **Y.S.P.SAH[®]**

Pharmacology (Summary of Pharmacodynamic and Pharmacokinetics):

- Antihistamine used in the treatment of allergy acts by competing with histamine for H₁-receptor sites on effector cells.
- The anticholinergic actions of most antihistamines provide a drying effect in the nasal mucosa, but loratadine has no significant anticholinergic activity.
- Loratadine is a long-acting antihistamine. It has been characterized as a specific, selective peripheral H₁-receptor antagonist and has been referred to as a relatively "non-sedating" or second generation antihistamine.
- Following single administration, loratadine exhibits antihistamine effects beginning within ½ ~ 1 hour, reaching a maximum at 8~10 hours, and lasting in excess of 24 hours.
- Distribution of loratadine has not been fully characterized. Protein binding of loratadine is about 97 ~ 99%. It appears to distribute poorly or not appreciably into the CNS at usual dosage. Small amount of it appears to be distributed into milk. The mean elimination half-life is 7.8 ~ 11 hours.
- Loratadine undergoes extensive metabolism by Cytochrome P450. The major metabolite, descarboethoxyloratadine (desloratadine) has potent antihistamine activity. Most of a dose is excreted equally in the urine and faeces, mainly in the form of metabolites.

Indications:

Relief of symptoms associated with allergic rhinitis e.g. sneezing, nasal discharge and itching, as well as ocular itching and burning. Chronic urticaria and other allergic dermatologic disorders.

Dosage and Administration:

Adults and children ≥ 12 years:

10mL [two 5mL spoonfuls (10mg)] once daily.

Children 2 ~ 12 years:

Body weight >30kg: 10mL [two 5mL spoonfuls (10mg)] once daily.

Body weight <30kg: 5mL [one 5mL spoonful (5mg)] once daily.

Route of administration: Oral**Precautions / Warnings:****WARNING**

Unsuitable for phenylketonurics

Drugs known to inhibit hepatic metabolism should be co-administered with caution until definitive interaction studies can be completed. The number of subjects who concomitantly received macrolide antibiotics, ketoconazole, cimetidine, ranitidine or theophylline along with loratadine in controlled clinical trials is too small to rule out possible drug interactions.

- Patients with severe liver impairment or renal impairment (creatinine clearance ≤ 30ml/min) should be administered a lower initial dose because they may have reduced clearance of loratadine, an initial dose of 5mg (5mL spoonful) once daily or 10mg (two 5mL spoonfuls) every other day is recommended.
- There are no adequate and controlled studies to date using loratadine in pregnant women, so it should be used during pregnancy only when the potential benefits justify the possible risks to the fetus.
- Caution should be exercised when loratadine is administered in a nursing woman because it is distributed readily into breast milk. Due to the increased risk of antihistamines for infants, particularly newborns and premature infants, a decision should be made whether to discontinue nursing or discontinue the drug.
- Safety and efficacy of loratadine in children < 2 years have not yet been established.
- Although drowsiness is rare, nevertheless patients should be advised that it can occur and may affect skilled tasks (e.g. driving).

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237mm ± 2mm