

DELINE® Tablets & Syrup

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about DELINE

Each DELINE tablet for oral use contains 5 mg desloratadine with the following excipients: calcium phosphate dibasic, microcrystalline cellulose, croscarmellose sodium, magnesium stearate

Each 1 mL of DELINE syrup for oral use contains 0.5 mg desloratadine with the following excipients: sucrose, citric acid, MP, PP, banana flavor, purified water.

Desloratadine, the active metabolite of loratadine, is a second generation antihistamine.

Desloratadine is a long-acting, non-sedative, selective histamine antagonist with peripheral H₁-receptor histamine antagonist activity.

Desloratadine blocks the action of histamine, a chemical released by the immune system when the body is affected by allergens.

In addition to antihistaminic activity, desloratadine has demonstrated antiallergic and anti-inflammatory activity. DELINE does not cause drowsiness.

DELINE is indicated for the fast relief of nasal and non-nasal symptoms associated with allergic rhinitis, including sneezing, nasal discharge and itching, congestion/stuffiness, itching of the palate, and coughing associated with these symptoms, as well as itching, tearing and redness of the eyes.

DELINE is indicated for use in adults and pediatric patients in the following cases:

- Relief of the nasal and non-nasal symptoms of seasonal or intermittent allergic rhinitis (such as allergy to trees, grass, pollen and ragweed).
- Relief of the nasal and non-nasal symptoms of perennial or persistent allergic rhinitis (such as allergy to dust mites, animal dander and molds).
- Symptomatic relief for urticarial conditions (chronic idiopathic urticaria, acute urticaria, cold-induced urticaria, demographic urticaria, solar-induced urticaria).

DELINE can be used by patients with allergic rhinitis who have concomitant mild to moderate asthma.

The way to take DELINE

Take DELINE as directed.

DELINE should be taken once daily without regard to meals.

The usual recommended doses are:

Age	Dose	DELINE tablet	DELINE syrup
Adults and children 12 years of age and older	5 mg once daily	1 tablet of 5 mg once daily	10 mL once daily
Children 6 to 11 years of age	2.5 mg once daily	Half a tablet of 5 mg once daily	5 mL once daily
Children 1 to 5 years of age	1.25 mg once daily	-	2.5 mL once daily
Infants 6 to 12 months of age	1 mg once daily	-	2 mL once daily

Dosage adjustment is recommended for adult patients with renal or hepatic impairment.

Duration of treatment

Since seasonal allergic rhinitis may be a chronic, recurrent condition, successful therapy often may require long-term, intermittent use of DELINE. In the treatment of seasonal allergic rhinitis, antihistamines are more likely to be beneficial when therapy is initiated at the

beginning of the hay fever season. The treatment could be discontinued after symptoms are resolved and reinitiated upon their reappearance.

In persistent allergic rhinitis, continued treatment may be proposed to the patients during the allergen exposure periods.

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

If you miss taking your dose on time take it when you remember. Do not exceed more than one dose in 24 hours.

Contraindications

This drug is contraindicated in case of known hypersensitivity to any of the components or to loratadine.

Precautions

- Consult your doctor before using this medication in case of pregnancy or lactation. This drug should be used during pregnancy only if clearly needed. Desloratadine passes into breast milk; therefore breast-feeding is not recommended in lactating women taking this drug.

- Caution should be taken in case of severe renal or hepatic insufficiency.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.

No clinically relevant interactions with desloratadine were observed.

Adverse reactions

DELIN is generally well tolerated. The most reported adverse effects were dry mouth, fatigue, and headache in adults; diarrhea, fever and insomnia in children.

Palpitations, hypersensitivity reactions and elevated liver enzymes have been rarely reported.

Inform your doctor if any side effect appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 30°C), protected from light and humidity, beyond the reach of children. The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

DELIN, desloratadine 5 mg, pack of 30 tablets.

DELIN, desloratadine 5 mg, pack of 10 tablets.

DELIN syrup, desloratadine 0.5 mg /mL, bottle of 120 mL with a dosing cup.

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