

Oradine

Loratadine USP

Non-Sedating - Antihistamine

DESCRIPTION

Oradine is a non - sedating, long-acting tricyclic antihistamine.

ACTIONS

Oradine exerts its antihistaminic effects by selectively antagonizing peripheral H₁-receptors.

Oradine is rapidly absorbed from the GI tract following oral administration. It can be administered independently of meals. Peak plasma concentrations appear within 1 to 3 hours, reaching a maximum at 8 to 12 hours, and lasting in excess of 24 hours.

Loratadine is 97% bound to plasma proteins and is extensively metabolized to an active metabolite, descarboethoxyloratadine. Both loratadine and its metabolite are excreted in the urine and feces with elimination half-lives of 8.4 and 20 hours respectively.

INDICATIONS

Oradine is indicated for the relief of symptoms associated with allergic rhinitis such as sneezing, nasal discharge and itching, as well as ocular itching and burning.

Oradine is also indicated for the relief of signs and symptoms of chronic idiopathic urticaria and other allergic dermatologic disorders.

CONTRAINDICATIONS

Oradine is contraindicated in patients with a known history of hypersensitivity to the medication or to any of its components.

PRECAUTIONS

- Patients with liver impairment or renal insufficiency should be given a lower initial dose.

- **Pregnancy:** Pregnancy category B: There was no evidence of teratogenicity in animals, however, there are no adequate and well controlled studies in pregnant women. **Oradine** could be used in pregnancy only if the benefit justifies the potential risk to the fetus.

- **Nursing Mothers:** As **Oradine** is excreted in breast milk, a decision should be made whether to discontinue the drug or discontinue nursing.

- Safety and effectiveness in children below 2 years of age have not yet been established.

ADVERSE REACTIONS

Headache, fatigue, dry mouth and GI disturbances (i.e., nausea, increased appetite, gastritis) are the most commonly reported side effects.

DOSAGE & ADMINISTRATION

*Tablets:

-Adults and children of 12 years and above: 1 tablet daily

-Patients with liver failure or renal insufficiency (GFR<30ml/min): 1 tablet every other day.

*Syrup:

-Adults and Children 6 years and over: 2 teaspoonfuls once daily.

-Children 2 to 6 years: 1 teaspoonful daily.

AVAILABILITY

*Tablets:

-Packs of 10 Tablets, each containing Loratadine USP 10 mg, Excipient q.s. 1 tablet.

Reg Lebanon 0767299

-Packs of 30 Tablets, each containing Loratadine USP 10 mg, Excipient q.s. 1 tablet.

Reg Lebanon 974087

*Syrup:

-Bottles of 100 ml, each 5 ml containing Loratadine Micronized USP 5 mg, Excipient q.s. 5 ml.

Reg Lebanon 194753

This is a medicament

-A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.

-Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

-The doctor and the pharmacist are experts in medicine, its benefits and risks.

-Do not by yourself interrupt the period of treatment prescribed for you.

-Do not repeat the same prescription without consulting your doctor.

* Oradine is a Trade Mark.

Keep medicaments out of reach of children

Pharmaline - Lebanon

Council of Arab Health Ministers
Union of Arab Pharmacists

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