RODELO®

[Desloratadine] 5mg Tablets

روڈیلو گولیاں

DESCRIPTION:
RODELO (Desloratadine) is a histamine antagonist.
QUALITATIVE AND QUANTITATIVE COMPOSITION:
RODELO (Desloratadine) is available for oral administration as:
RODELO Tablet 5mg
Each film coated tablet contains:
Desloratadine USP.....5mg
(Product Specs.: USP)
CLINICAL PHARMACOLOGY:
Mechanism of Action:
Desloratadine is a non-sedating, long-acting tricyclic histamine antagonist with selective H_1-receptor histamine antagonist activity. Desloratadine inhibited histamine release from human mast cells in-vitro.
Pharmacokinetics:
Absorption:
Desloratadine is well absorbed with maximum concentration achieved after approximately 3 hours. The bioavailability of desloratadine was dose proportional over the range of 5mg to 20mg.
Distribution:
Desloratadine and 3-hydroxydesloratadine are approximately 82% to 87% and 85% to 89% bound to plasma proteins.
Metabolism:
Desloratadine is extensively metabolized to 3-hydroxydesloratadine an active metabolite, which is subsequently glucorinated.
Excretion:
The mean elimination half-life of desloratadine was 27 hours. C_{max} and AUC values increased in dose proportional manner following single oral doses between 5mg to 20mg. The degree of accumulation after 14 days of dosing was consistent with the half-life and dosing frequency.
Special Population:
Renal Impairment:
In patients with mild and moderate renal impairment, median C_{max} and AUC values increased relative to subjects with normal renal function. In patients with severe renal impairment or who were hemodialysis dependent, C_{max} and AUC values also increased. Desloratadine and 3-hydroxydesloratadine were poorly removed by hemodialysis. Dosage adjustment for patients with renal impairment is recommended.
Hepatic Impairment:
An increase in the mean elimination half-life of desloratadine in patients with hepatic impairment was observed. Dosage adjustment for patients with hepatic impairment is recommended.
THERAPEUTIC INDICATIONS:
- **Seasonal Allergic Rhinitis:**
RODELO (Desloratadine) tablets are indicated for the relief of the nasal and non-nasal symptoms of seasonal allergic rhinitis in patients 12 years of age or older.
- **Perennial Allergic Rhinitis:**
RODELO (Desloratadine) tablets are indicated for the relief of the nasal and non-nasal symptoms of perennial allergic rhinitis in patients 12 years of age or older.
- **Chronic Idiopathic Urticaria:**
RODELO (Desloratadine) tablets are indicated for the symptomatic relief of pruritis, reduction in the number of hives, in patients with chronic idiopathic urticaria 12 years of age and older.
DOSAGE AND ADMINISTRATION:
The recommended dose of **RODELO** (Desloratadine) tablets is one 5mg tablet once daily with or without a meal.
Special Population:
- **Patients with Renal and Hepatic Impairment:**
In patients with renal or hepatic impairment, a starting dose of one 5mg tablet every other day is recommended based on pharmacokinetic data.

CONTRAINDICATIONS:
- Desloratadine is contraindicated in patients who have shown hypersensitivity or idiosyncrasy to desloratadine, to loratadine or to any of the excipients.
- Children under 12 years of age.
PRECAUTIONS:
Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.
Pregnancy:
Desloratadine should be used during pregnancy only if the potential benefit justifies the risk to the fetus.
Lactation:
Desloratadine passes into human breast milk; therefore, a decision should be made whether to discontinue desloratadine, taking into account the importance of the drug to the mother.
ADVERSE REACTIONS:
The most common side effects reported were fatigue, headache and dry mouth. Other adverse effects reported very rarely were: Hallucinations, dizziness, somnolence, insomnia, psychomotor, hyperactivity, seizures, tachycardia, palpitations, abdominal pain, nausea, vomiting, dyspepsia, diarrhea, elevations of liver enzymes, increased bilirubin, hepatitis, myalgia, hypersensitivity reactions (such as anaphylaxis, angioedema, dyspnoea, pruritus, rash and urticaria).
OVERDOSAGE:
In the event of overdose, consider standard measures to remove any unabsorbed drug. Symptomatic and supportive treatment is recommended. Desloratadine and 3-hydroxydesloratadine are not eliminated by hemodialysis.
INSTRUCTIONS:
- Store below 30°C.
- Protect from light & moisture.
- Keep out of reach of children.
To be sold on prescription of a registered medical practitioner.

HOW SUPPLIED:
RODELO (Desloratadine) Tablets 5mg are available in pack of 10's.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات: دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
انتباہ: صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

SIGMA PHARMA
Manufactured by:
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