LEVOGEX®-5 mg levocetirizine dihydrochloride (film-coated tablet)

Approved indication

Each film-coated tablet contains 5 mg levocetirizine dihydrochloride.1 Levogex® is indicated in adults for relief of symptoms associated with:

- Seasonal allergic rhinitis
- Perennial allergic rhinitis
- Chronic idiopathic urticaria

Mode of action

Levocetirizine is an H1-receptor antagonist and the (R) enantiomer of cetirizine.1,2 An in vitro study showed that levocetirizine exhibited a 2-fold higher affinity for H1-receptors than cetirizine.2

Dosage

Adults or children 12 years of age or older: The recommended dose is one 5 mg tablet taken orally once daily.1

Evidence of efficacy

Allergic rhinitis: In an open-label meta-analysis of 92 900 patients, monotherapy with levocetirizine 5 mg was demonstrated to be significantly more effective in reducing the Total Symptom Score (p <0.001) and the Total Nasal Symptom Score (p < 0.05) than other second-generation antihistamines (desloratadine, ebastine, fexofenadine). The effect of levocetirizine on its own, as compared to its combination with nasal steroids, was found to be stronger in reducing nasal symptoms.3

Wheal and flare: A randomised double-blinded study with desloratadine 5 and 10 mg and levocetirizine 5 and 10 mg showed that levocetirizine 5 and 10 mg was more effective in suppressing histamine-induced wheal and flare reactions compared to desloratadine 5 and 10 mg.4

Chronic idiopathic urticaria: A prospective, open, comparative, randomised study of levocetirizine and rupatadine in chronic idiopathic urticaria found levocetirizine to be more effective than rupatadine.5 Similarly, an open, randomised study comparing the efficacy of loratadine and levocetirizine in chronic idiopathic urticaria, found levocetirizine to be superior in efficacy for chronic idiopathic urticaria.6

Precautions

General

Renal impairment: Dosing intervals need to be adjusted in patients with renal impairment. Levogex® is contra-indicated in patients with severe renal impairment or receiving dialysis, and a creatinine clearance of less than 10 ml/min.1

Hepatic impairment: No dosage adjustment is needed in patients with hepatic impairment.1

Paediatric patients: Levogex® is contra-indicated in children under 12 years of age, as safety and efficacy in this age group have not been established.1

Lactose intolerance: Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency, or glucose-galactose malabsorption should not take Levogex®, as this medication contains lactose monohydrate.1

Effects on ability to drive and use machines: Although Levogex® lacks significant sedative effects, each individual would need to establish their individual reaction to the medication before driving or performing hazardous tasks. Certain individuals may experience sedation, somnolence and fatigue.1

Pregnancy and lactation

Levogex® is contra-indicated in pregnancy, as safety in this group has not been established.1 Levocetirizine is excreted in breast milk and is therefore contraindicated in breastfeeding women.1

Major adverse effects

Frequent side-effects reported include headache, somnolence, dry mouth, nausea, fatigue and myalgia. Less frequent side-effects include nausea and gastrointestinal discomfort, asthenia and malaise. Amongst others, the following side-effects have also been reported, the frequency of which is not known: hypersensitivity and skin reactions, angioedema, anaphylaxis, gastro-intestinal discomfort, convulsions, aggression, agitation, hallucination, depression, convulsions, palpitations, tachycardia, visual disturbances, dyspnœa, hepatitis, abnormal liver function, urticaria, pruritus, rash, weight increase.1
Drug interactions

- Interaction with other medicines has not been recorded.
  No clinically relevant interactions between Levogex® and ketoconazole, erthyromycin, azithromycin, cimetidine or pseudoephedrine have been demonstrated.¹
- Simultaneous intake of Levogex® and alcohol or other CNS depressants may increase the central nervous system (CNS) depressant effects of Levogex®.¹

Cost: SEP (Incl VAT)

R24.90 per 10 Levogex® 5 mg tablets
R74.70 per 30 Levogex® 5 mg tablets⁷

Patient information

Levogex® may be taken with or without food. Swallow with a liquid.¹ Patients should not drink alcohol or take other CNS depressants while taking this medication.² Exercise caution before driving or using machinery when taking Levogex® until drug effects are realised.² Levogex® tablets should not be taken for longer than 6 weeks.³

References:

1. Levogex® Tablets approved package insert, October 2015.

¹ Levogex Tablets. Each film-coated tablet contains levocetirizine dihydrochloride 5 mg. Reg. No. 46/5.7.1/0300.
For full prescribing information refer to the package insert approved by the medicines regulatory authority. 10267193 05/2016