



11700

The dosing intervals must be individualized according to renal function. Refer to the following table and adjust the dose as indicated. To use this dosing table, an estimate of the patient's creatinine clearance (CL_{cr}) in ml/min is needed. The CL_{cr} (ml/min) may be estimated from serum creatinine (mg/dl) determination using the following formula:



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CLcr = $\frac{[140 - \text{Age (years)}] \times \text{weight (kg)}}{72 \times \text{serum creatinine}}$ (x 0.85 for women)

Dosing adjustments for patients with impaired renal function:

Group	Creatinine clearance (ml/min)	Dosage and frequency
Normal	≥ 80	1 tablet once daily
Mild	50- 79	1 tablet once daily
Moderate	30- 49	1 tablet once every 2 days
Severe	<30	1 tablet once every 3 days
End-stage renal disease	< 10	Contra-indicated
Patients undergoing dialysis		

Patients with hepatic impairment:

No dose adjustment is needed in patients with solely hepatic impairment. In patients with hepatic impairment and renal impairment, adjustment of the dose is recommended (see patients with renal impairment above).

Duration of use:

The duration of use depends on the type, duration and course of the complaints. For hay fever 3-6 weeks, and in case of short-term pollen exposure as little as one week, is generally sufficient. Clinical experience is available for chronic urticaria and chornic allergic rhinitis, racemate and in pruruitus associated with atopic dermatitis.

Route of administration:

Oral

Contra-indications:

History of hypersensitivity to levocetirizine or any of the other constituents of the formulation or to any piperazine derivatives. Patients with severe renal impairment at less than 10 ml/ min creatinine clearance.

Warnings and precautions:

The use of Levocetirizine Tablet is not recommended in children aged less than 6 years since the currently available film-coated tablets do not yet allow dose adaptation.

Precaution is recommended with intake of alcohol (see interactions). Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose- galctose malabsorption should not take this medicine.

Effects on ability to drive and use machines:

Activities Requiring Mental Alertness: In clinical trials the occurrence of somnolence has been reported in some patients taking cetirizine: due caution should therefore be exercised when driving a car or operating potentially dangerous machinery.

Interactions with other medicinal products and other forms of interaction:No interactions studies have been performed with levocetirizine (including no studies with CYP3A4 inducer); studies with the racemate compound cetirizine demonstrated that there were no clinically relevant adverse interactions (with pseudoephdrine, cimetidine, ketoconazole, erythromycin, azithromycin, glipizide and diazepam). A small decrease in the clearance of cetirizine (16%) was observed in a multiple dose study with theophylline (400 mg once a day); while the disposition of theophylline was not altered by concomitant cetirizine administration. The extent absorption of levocetirizine is not reduced with food, although the rate of absorption is decreased. In sensitive patients the simultaneous administration of cetirizine or levocetirizine and alcohol or other CNS depressants may have effects on the central nervous system, although it has been shown that the racemate cetirizine does not potentiate the effect of alcohol.

Pregnancy and Lactation:

For Levocetirizine no clinical data exposed on pregnancies are available. However, caution should be exercised when prescribing to pregnant or lactating women.

Undesirable effects:

From clinical studies, mainly mild to moderate side effects such as dry mouth, headache, fatigue and somnolence have been reported commonly (above 1%). Further uncommon incidences of adverse reactions like asthenia or abdominal pain were observed.

In addition to the adverse reported during clinical studies and listed above, very rare cases of the following adverse drug reactions have been reported in post-marketing experience: hypersensitivity including anaphylaxis, dyspnoea, nausea, angioneurotic oedema, pruritus, rash, urticaria and weight increased.

Overdose:

Symptoms

Symptoms of overdose may include drowsiness in adults and initially agitation and restlessness, followed by drowsiness in children.

Management of overdose

There is no known specific antidote to levocetirizine.

Should overdose occur, symptomatic or supportive treatment is recommended. Gastric lavage should be considered following short-term ingestion.

Levocetirizine is not effectively removed by haemodialysis.

Storage conditionsStore in a dry place below 25°C and protected from light

Shelf life:

2 years from the date of manufacture.

Presentation:

Blister of 10 tablets, 3 such blisters are packed in a printed carton along with the package insert.

PRODUCT REGISTRATION HOLDER

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Date of preparation: 25/06/2024

