

Product :  
Cetyrec Tab 5mg Insert

Size: 160mm (w) x 250mm (h)

## CETYREC-AP FILM-COATED TABLET 5MG

Levocetirizine dihydrochloride (5 mg)



### Name and strength of active ingredient

Each film-coated tablet contains Levocetirizine dihydrochloride 5 mg

### Product description

Biconvex, oval, white film coated tablet. One side has score and letter "L" and "C" on each side. Another side has figure "5".

### Pharmacodynamic/Pharmacokinetics

#### Pharmacodynamic

#### Mechanism of action

Levocetirizine is the active R-enantiomer of cetirizine, a second generation antihistamine. The drug is selective antagonism of histamine H1-receptors and as a group, is less sedating.

#### Pharmacokinetics

Levocetirizine is rapidly and extensively absorbed following oral administration, with peak plasma concentration usually attained in 0.9 hour. A high-fat meal reduces peak plasma concentration by about 36% and delays time to peak plasma concentration by about 1.25 hours, but does not affect AUC. A high-fat meal delays drug absorption but completely absorbed. The average apparent volume of distribution is 0.4 L/kg. Levocetirizine is approximately 91 - 92% bound to plasma proteins (mainly albumin). The extent of metabolism of levocetirizine is less than 14% of dose by aromatic oxidation, N-dealkylation, O-dealkylation and taurine conjugation. Levocetirizine is excreted in urine; 85.4% (via glomerular filtration and active tubular secretion) and excreted in the feces 12.9%. The elimination half-life is 8 – 9 hours in adults.

#### Indication

Levocetirizine is indicated for the symptomatic treatment of allergic rhinitis (including persistent allergic rhinitis) and chronic idiopathic urticaria.

#### Recommended Dose

##### Dosage and Administration

Levocetirizine dihydrochloride, 5 mg, film-coated tablet  
The film-coated tablet must be taken orally, swallowed whole with liquid and may be taken with or without food. It is recommended to take the daily dose in one single intake.

##### Duration of use

Intermittent allergic rhinitis (symptoms <4 days/week or for less than 4 weeks a year) has to be treated according to the disease and its history; it can be stopped once the symptoms have disappeared and can be restarted again when symptoms reappear.

In case of persistent allergic rhinitis (symptoms >4 days/week or for more than 4 weeks a year), continuous therapy can be proposed to the patient during the period of exposure to allergens.

There is clinical experience with the use of levocetirizine for treatment periods of at least 6 months.

In chronic urticaria and chronic allergic rhinitis, there is clinical experience of use of cetirizine (racemate) for up to one year.

**Route of Administration:** For oral use.

**Adults and adolescents 12 years of age and above:** The daily recommended dose is 5 mg (1 film-coated tablet).

**Children aged 6 - 12 years:** The daily recommended dose is 5 mg (1 film-coated tablet).

**Elderly:** Adjustment of the dose is recommended in elderly patients with moderate to severe renal impairment.

**Renal impairment:** 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 (CLcr) in ml/min is needed. The CLcr (ml/min) may be estimated from serum creatinine (mg/dl) determination using the following formula:

$$CL\ cr = \frac{[140 - \text{age (years)}] \times \text{weight (kg)}}{72 \times \text{serum creatinine (mg/dl)}} \times (0.85 \text{ for women})$$

Dosing adjustments for patients with impaired renal function:

Group	Creatinine clearance (ml/min)	Dosage and frequency
Normal	≥ 80	5 mg once daily
Mild	50 – 79	5 mg once daily
Moderate	30 – 49	5 mg once daily every 2 days
Severe	< 30	5 mg once daily every 3 days
End-stage renal disease - Patients undergoing dialysis	< 10	Contraindicated

In patients with hepatic impairment and renal impairment, adjustment of the dose is recommended.

#### Mode of Administration

Levocetirizine dihydrochloride is administered orally once daily in the evening without regard to meals.

#### Contraindication

- Levocetirizine is contraindicated in patients who are hypersensitive to levocetirizine or any ingredient in the formulation or to cetirizine.
- Levocetirizine is contraindicated in patients with in end-stage renal disease (creatinine clearance

less than 10 mL/min) or undergoing hemodialysis.

3) Levocetirizine is contraindicated in children 6 months to 11 years of age with renal impairment.

#### Warning and Precaution

1) Patients receiving of levocetirizine may have somnolence. Avoid performing hazardous activities (e.g., operating machinery, driving a motor vehicle or work in high places)

2) Concomitant use of levocetirizine with alcohol or other CNS depressants should be avoided.

3) Use with caution in patients with predisposing factors of urinary retention (eg, spinal cord lesion, prostatic hyperplasia) as levocetirizine may increase the risk of urinary retention. Discontinue if urinary retention occurs.

#### Ability to perform tasks that require judgement, motor or cognitive skills

Comparative clinical trials have revealed no evidence that levocetirizine at the recommended dose impairs mental alertness, reactivity or the ability to drive. Nevertheless, some patients could experience somnolence, fatigue and asthenia under therapy with levocetirizine. Therefore, patients intending to drive, engage in potentially hazardous activities or operate machinery should take their response to the medicinal product into account.

#### Interactions with Other Medication

1) No interaction studies have been performed with levocetirizine (including no studies with CYP3A4 inducers).

2) Studies with the racemate compound cetirizine demonstrated that there were no clinically relevant adverse interactions (with antipyrine, pseudoephedrine, cimetidine, ketoconazole, erythromycin, azithromycin, glipizide and diazepam).

3) Concomitant administration of cetirizine and ritonavir may increase the AUC and half-life and decreased the clearance of cetirizine; the disposition of ritonavir was not altered.

4) Concomitant use of cetirizine and theophylline resulted in decrease clearance (16%) of cetirizine; the disposition of theophylline was not altered.

#### Pregnancy and Lactation

Pregnancy Category B. Safety for use drug pregnancy has not been established.

Levocetirizine is expected to be distributed into milk (since cetirizine is distributed into milk). The use of levocetirizine in breast-feeding mother is not recommended.

#### Undesirable Effects

##### Common;

**Gastrointestinal:** Constipation (infants 6.7%, children 0.9%), Diarrhea (infants 13.3%, children 3.5%), Painful teething (infants 6.7%, children 1.8%)

**Neurologic:** Asthenia (2.3%), Somnolence (infants 4.4%, children 3%, adults 5% – 6%)

**Respiratory:** Nasopharyngitis (4% – 6%), Pharyngitis (1% to 2%), Xerostomia (2% – 3%)

**Other:** Fatigue (1% – 4%), Fever (Children 4% – 4.4%)

#### Overdose and Treatment

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

**Treatment:** There is no known specific antidote to levocetirizine. Should overdose occur, symptomatic or supportive treatment is recommended. Levocetirizine is not effectively removed by haemodialysis.

#### Storage Condition

Store at a temperature below 30 °C

#### Dosage Forms and Packaging Available

**Dosage forms:** Film-coated tablets

**Packaging Available:** 10 tablets in Aluminium-Aluminium blister, which packed in carton box of 5 blisters.

#### Date of revision of package insert

Revision: 002

Date of revision: 21 November 2024

#### Manufactured by:

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