

Levocetirizine diHCl 5 mg, film-coated tablets

(Levocetirizine dihydrochloride)

What is levocetirizine diHCl 5 mg and what is it used for?

Levocetirizine dihydrochloride is the active substance of Levocetirizine diHCl 5 mg. Levocetirizine diHCl 5 mg is a medication used for the treatment of allergy-related symptoms. This medication is used for the treatment of symptoms related to:

- Inflammation of the nasal mucosa caused by an allergy (allergic rhinitis, including persistent allergic rhinitis);
- Hives (urticaria).

When should you not take this medicine or be extra careful with it?

When should you not use this medicine

- You are allergic to any of the substances in this medicine.
- You have severe problems with the functioning of your kidneys (severe renal failure with a creatinine clearance below 10 ml/min).

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before taking this medicine.

If you have a chance of being unable to empty your bladder (e.g., in case of spinal cord injury or enlarged prostate), consult your doctor for advice.

Children: The use of Levocetirizine diHCl 5 mg is not recommended for children under 6 years of age since the tablets do not allow for dose adjustment.

Are you taking any other medicines?: Are you taking any other medicines besides Levocetirizine diHCl 5 mg, or have you done so recently or is there a possibility that you will take other medicines in the near future? Then tell your doctor or pharmacist.

What should you be aware of with food, drink, and alcohol?: Caution is advised when taking Levocetirizine diHCl 5 mg together with alcohol. In sensitive patients, simultaneous use of cetirizine or levocetirizine with alcohol or other central nervous system agents may have effects on the central nervous system, although racemic cetirizine has been shown not to enhance the effect of alcohol.

Pregnancy and breastfeeding: Are you pregnant, think you may be pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before taking this medicine.

Driving ability and use of machines: In some patients treated with Levocetirizine diHCl 5 mg, there may be drowsiness, fatigue, and exhaustion. If you plan to drive a vehicle, perform potentially hazardous activities, or operate machinery, wait and see how you react to this medicine. However, in special tests with healthy subjects and after taking levocetirizine in the recommended dosage, no indications were found that mental alertness, reaction time, or driving ability was impaired.

Levocetirizine diHCl 5 mg contains lactose. If your doctor has told you that you have an intolerance to certain sugars, contact your doctor before using this medicine.

How to take this medicine?

Always take this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

The recommended dosage for adults and children 6 years and older is 1 tablet per day.

Special dosage instructions for specific patient groups

- Patients with reduced kidney function may need a lower dose, depending on the severity of their kidney disease. In children, the dose is also determined based on body weight. Your dose is determined by your doctor.
- Patients who have severe problems with the way their kidneys work should not take Levocetirizine diHCl 5 mg.
- Patients with only liver dysfunction should take the usual prescribed dosage.
- Patients who have both liver dysfunction and kidney dysfunction may receive a lower dose, depending on the severity of their kidney disease. In children, the doctor determines the dosage based on body weight.

Use in children: Levocetirizine is not recommended for children under 6 years of age.

Older patients: Dose adjustment is not necessary for older patients, provided their kidney function is normal.

How to take this medicine?

The tablet should be swallowed with water and can be taken with or without food.

Did you take too much of this medicine?

If you have taken more Levocetirizine diHCl 5 mg than you should, drowsiness may occur. In children, initial excitement and restlessness may occur, followed by drowsiness.

If you think you have taken an overdose of Levocetirizine diHCl 5 mg, contact your doctor. They will then decide what action to take.

Did you forget to take this medicine?: Do not take a double dose to make up for a missed dose or when you have taken less than prescribed by your doctor. Take your next dose at the usual time, as prescribed by your doctor.

If you stop taking this medicine: Stopping treatment should not have any adverse effects. The symptoms may return, but they should not be worse than before treatment. Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

Possible Side Effects

Like all medicines, this medicine can have side effects, although not everyone gets them. Stop using Levocetirizine diHCl 5 mg and contact your doctor immediately if you experience any of the following signs of an allergic reaction during the use of this medicine: swelling of the mouth, tongue, face and/or throat, breathing or swallowing problems (chest tightness or wheezing), hives, sudden drop in blood pressure, resulting in fainting or shock, which can be fatal

Other possible side effects include:

Often (may occur in 1 out of 10 users): • Dry mouth, headache, fatigue, and drowsiness

Sometimes (may occur in 1 out of 100 users): • Exhaustion and abdominal pain

how to store this medicine?

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the box after "EXP.". The month and year are given. The last day of that month is the expiry date.
- There are no special storage conditions for this medicine.
- Do not flush medicines down the sink or toilet or throw them in the trash. Ask your pharmacist how to dispose of medicines that are no longer needed. They will be disposed of responsibly and will not harm the environment.