

Package leaflet: Information for the patient

Levocetirizine dihydrochloride 5 mg film-coated tablets

Levocetirizine dihydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of this medicine is Levocetirizine dihydrochloride 5mg film-coated tablets, which will be referred to as Levocetirizine tablets

What is in this leaflet

1. What Levocetirizine tablet is and what it is used for
2. What you need to know before you take Levocetirizine tablets
3. How to take Levocetirizine tablets
4. Possible side effects
5. How to store Levocetirizine tablets
6. Contents of the pack and other information

1. What Levocetirizine tablet is and what it is used for

This medicine contains levocetirizine dihydrochloride as the active ingredient

It is an antiallergic medication.

This medicine is used for treatment of signs of illness (symptoms) associated with:

- allergic rhinitis (including persistent allergic rhinitis);
- nettle rash (urticaria).

2. What you need to know before you take Levocetirizine tablets

Do not take Levocetirizine tablets

- if you are allergic (hypersensitive) to levocetirizine dihydrochloride, an antihistamine or any of the other ingredients of this medicine (listed in section 6).
- if you have a severe impairment of kidney function (severe renal failure with creatinine clearance below 10 ml/min).

Warnings and precautions

Talk to your doctor or pharmacist before taking Levocetirizine tablets.

If you are likely to be unable to empty your bladder (with conditions such as spinal cord injury or enlarged prostate), please ask your doctor for advice.

Children

The use of Levocetirizine tablets is not recommended in children less than 6 years since the film-coated tablets do not allow for dose adaptation. It is recommended to use children formulation of levocetirizine

Other medicines and Levocetirizine tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Levocetirizine tablets with food, drink and alcohol

You must be cautious if you take Levocetirizine tablet at the same time as alcohol.

In sensitive patients, the simultaneous use of cetirizine (a similar drug) or levocetirizine and alcohol or other centrally acting agents may have effects on the central nervous system, although cetirizine has been shown not to increase the effect of alcohol.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. .

Driving and using machines

Some patients being treated with Levocetirizine tablets may experience somnolence / drowsiness, tiredness and exhaustion. If you are intending to drive, engage in potentially hazardous activities or use machines you are therefore advised first to wait and observe your response to the medication. However, special tests have revealed no impairment of mental alertness, the ability to react or the ability to drive in healthy test persons after taking levocetirizine in the recommended dosage.

Levocetirizine tablets contains lactose

This medicine contains lactose monohydrate and anhydrous lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Levocetirizine tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults and children over 6 years

The recommended dose for adults and children aged 6 years and over is one tablet daily.

Levocetirizine tablet is not recommended for children under 6 years of age

Patients with impaired kidney function may be given a lower dose according to the severity of their kidney disease, and in children the dose will also be chosen on the basis of body weight; the dose will be determined by your doctor.

Patients who only have impaired liver function should take the usual prescribed dose.

Patients who have both impaired liver and kidney function may be given a lower dose depending on the severity of the kidney disease, and in children the dose will also be chosen on the basis of body weight; the dose will be determined by your doctor.

Method of administration:

The tablets should be swallowed whole with water and may be taken with or without food.

If you take more Levocetirizine tablets than you should:

A substantial overdose may cause drowsiness in adults. Children may initially show excitement and restlessness followed by drowsiness.

If you think you have taken an overdose of Levocetirizine tablets, please tell your doctor who will then decide what action should be taken.

If you forget to take Levocetirizine tablets:

If you forget to take Levocetirizine tablets, or if you take a dose lower than that prescribed by your doctor, do not take a double dose to compensate; just take the next dose at the usual time, as prescribed by your doctor.

Do not take a double dose to make up for a forgotten tablet.

If you stop taking Levocetirizine tablets:

If you stop the treatment with Levocetirizine tablets earlier than foreseen this should not cause any harmful effects. However, the symptoms of the disease may progressively reappear with a severity not higher than the one experienced prior to treatment with Levocetirizine tablets.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

At the first signs of a hypersensitivity (allergic) reaction, stop taking Levocetirizine and **tell your doctor immediately**. Hypersensitivity (allergic) reaction symptoms may include:

- swelling of the mouth, tongue, face and/or throat,
- breathing or swallowing difficulties together with hives (angioedema),
- sudden fall in blood pressure leading to collapse or shock, which may be fatal.

The following side effects have been reported:

Common (may affect up to 1 in 10 people), mainly mild to moderate

- dry mouth,
- headache,
- tiredness
- somnolence/drowsiness.

Uncommon (may affect up to 1 in 100 people)

- exhaustion
- abdominal pain.

Not known: frequency cannot be estimated from the available data.

- palpitations,
- increased heart rate,
- convulsions,
- visual disturbances,
- oedema,
- pruritus (itchiness),
- rash,
- urticaria (swelling, redness and itchiness of the skin),
- skin eruption,
- shortness of breath,
- weight increase,
- muscular pain,
- aggressive or agitated behaviour,
- hallucination,
- depression,
- hepatitis,
- abnormal liver function,
- nausea,

- vomiting,
- recurring thoughts of or preoccupation with suicide.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie .

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Levocetirizine tablets

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after Exp. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions.

Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Levocetirizine tablet contains

- The active substance is levocetirizine dihydrochloride.
- Each film-coated tablet contains 5 mg levocetirizine dihydrochloride.
- The other ingredients are anhydrous lactose, lactose monohydrate, microcrystalline cellulose, crospovidone (Type A), magnesium stearate, hypromellose (E464), titanium dioxide (E171) and macrogol 6000.

What Levocetirizine tablets looks like and contents of the pack

White, oval shaped, biconvex, film coated tablets debossed with 'C5' on one side and plain on other side.

They are supplied in blister packs of 7, 10, 14, 20, 28, 30, 50, 56, 84, and 100 tablets in an outer carton.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Cipla (EU) Limited, Hillbrow House, Hillbrow Road, Esher, Surrey, KT10 9NW, United Kingdom

Manufacturer

Cipla (EU) Ltd, 20 Balderton Street, London W1K 6TL, United Kingdom

S&D Pharma CZ, spol. s r.o, Theodor 28, Pchery (Pharmos a.s. facility), 27308, Czech Republic

Cipla Europe NV, Uitbreidingstraat 80, 2600 Antwerp, Belgium

This medicinal product is authorised in the Member States of the EEA under the following names:

UK	Levocetirizine Dihydrochloride 5 mg film-coated tablets
IE	Levocetirizine Dihydrochloride 5 mg film-coated tablets
ES	Levocetirizina dihidrocloruro Cipla 5 mg comprimidos recubiertos con película
EL	LEVOCETIRIZINE DIHYDROCHLORIDE 5 mg επικαλυμμένα μελεπτό υμένιοδισκία
PT	Levocetirizina Cipla
FR	LEVOCETIRIZINE CIPLA 5 mg, comprimé pelliculé
IT	LEVOCETIRIZINA CIPLA
MT	Levocetirizine Dihydrochloride 5 mg film-coated tablets
PL	Levocetirizine Dihydrochloride Cipla
CZ	Levocetirizin Cipla Europe 5 mg
SK	Levocetirizín dihydrochlorid Cipla 5 mg filmom obalené tablety
HU	Levocetirizin Cipla 5 mg filmtabletta
BG	Леводетиризин Cipla
RO	Levocetirizina Cipla 5 mg Comprimate filmate
HR	Levocetirizin dihidroklorid Cipla 5 mg filmom obložene tablete

This leaflet was last revised in 07/2015