Package leaflet: Information for the patient

Levocetirizine Krka 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.

What is in this leaflet:

1. What Levocetirizine Krka is and what it is used for
2. What you need to know before you take Levocetirizine Krka
3. How to take Levocetirizine Krka
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1. What Levocetirizine Krka is and what it is used for

Levocetirizine dihydrochloride is the active ingredient of Levocetirizine Krka.
Levocetirizine Krka is an antiallergic medicinal product.

For the 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 Krka

Do not take Levocetirizine Krka:
- if you are allergic to levocetirizine dihydrochloride or to any other antihistamine or to any of the other ingredients of this medicine (listed in section 6),
- if you have 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 Krka.

The use of Levocetirizne Krka is not recommended for children under 6 years since the film-coated tablets do not allow dose adaptation.

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.

Other medicines and Levocetirizine Krka
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Levocetirizine Krka with food, drink and alcohol

Caution is advised if Levocetirizine Krka is taken at the same time as alcohol or other agents acting on the brain.
In sensitive patients, the concurrent administration of Levocetirizine Krka and alcohol or other agents acting on the brain may cause additional reductions in alertness and impairment of performance. Levocetirizine Krka can be taken with or without food.

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.

Tell your doctor if you are pregnant, trying to get pregnant or breast-feeding.

Driving and using machines
Some patients being treated with Levocetirizine Krka may experience somnolence/drowsiness, tiredness and exhaustion. If you intend to drive, engage in potentially hazardous activities or use machinery, 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 Krka contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take levocetirizine krka

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

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

Elderly patients aged 65 years and above
No adaptation of the dose is necessary in elderly patients, provided their renal function is normal.

Renal and hepatic impairment
Patients with impaired kidney function may be given a lower dose, according to the severity of their 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 have severe impairment of kidney function must not take Levocetirizine Krka.

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 the doctor.

Use in children
Levocetirizine Krka tablets are not recommended for children under 6 years of age.

How and when should you take Levocetirizine Krka?
For oral use only.
The tablets should be swallowed whole with water and may be taken with or without food.

How long should you take Levocetirizine Krka?

The duration of use depends on the type, duration and course of your complaints and is determined by your physician.

If you take more Levocetirizine Krka than you should
If you take more Levocetirizine Krka as you should, somnolence can occur in adults.
Children may initially show excitation and restlessness followed by somnolence.

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

If you forget to take Levocetirizine Krka
If you forget to take Levocetirizine Krka, or if you take a dose lower than that prescribed by your doctor, do not take a double dose to compensate; just wait for the foreseen time for intake of the next dose, and take a normal dose as prescribed by your doctor.

If you stop taking Levocetirizine Krka
Stopping treatment should have no negative effects. Symptoms may return, but they should not be any worse than they were prior to treatment.

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.

Common side effects (may affect up to 1 in 10 people):
Dry mouth, headache, tiredness and somnolence/drowsiness

Uncommon side effects (may affect up to 1 in 100 people):
Exhaustion and abdominal pain

Not known (frequency cannot be estimated from the available data):
Other side effects such as palpitations, increased heart rate, fits, pins and needles, dizziness, syncope, tremor, dysgeusia (distortion of the sense of taste), sensation of rotation or movement, visual disturbances, blurred vision, painful or difficult urination, inability to completely empty the bladder, oedema, pruritus (itchiness), rash, urticaria (swelling, redness and itchiness of the skin), skin eruption, shortness of breath, weight increase, muscular pain, joint pain, aggressive or agitated behaviour, hallucination, depression, insomnia, recurring thoughts of or preoccupation with suicide, hepatitis, abnormal liver function, vomiting, increased appetite, nausea and diarrhoea, have also been reported.

At the first signs of a **hypersensitivity reaction**, stop taking Levocetirizine Krka and see your doctor immediately. Hypersensitivity reaction symptoms may include: swelling of the mouth, tongue, face and/or throat, breathing or swallowing difficulties (chest tightness or wheezing), hives, sudden fall in blood pressure leading to collapse or shock, which may be fatal.

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 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 krka

Keep this medicine out of the sight and reach of children.

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

This medicine does not require any special storage conditions.

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

6. Contents of the pack and other information

What Levocetirizine Krka contains
- The active substance is levocetirizine dihydrochloride. Each film-coated tablet contains 5 mg levocetirizine dihydrochloride.
- The other ingredients are lactose monohydrate; cellulose, microcrystalline; silica, colloidal anhydrous and magnesium stearate in the tablet core; and lactose monohydrate; hypromellose 6cP; titanium dioxide (E171); macrogol 3000 and triacetin in the film-coating (see section 2).

What Levocetirizine Krka looks like and contents of the pack
The tablets are white, round, biconvex film-coated tablets with bevelled edges.
The tablets are available in packs of 7, 10, 14, 20, 28, 30, 50, 60, 90, 98 and 100 film-coated tablets in blisters.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Manufacturer
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

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

Name of the member state	Name of the medicinal product
Czech Republic	Cezera 5 mg potahované tablety
Hungary	Cezera 5 mg filmtabletta
Poland	Cezera
Rumania	Cezera 5 mg comprimate filmate
Slovenia	Cezera 5 mg filmsko obložene tablete
Slovak Republic	Cezera 5 mg filmom obalené tablety
Bulgaria	ЦЕЗЕРА 5 mg филмираии таблетки
Lithuania	Cezera 5 mg plėvele dengtos tabletės
Estonia	Cezera 5mg
Denmark	Levocetirizin Krka, filmovertrukne tabletter
Austria	Levocetirizin Krka 5 mg filmtabletten
Spain	Levocetirizina Krka 5 mg comprimidos recubiertos con película EFG

Ireland	Levocetirizine Krka 5 mg film-coated tablets
United Kingdom	Levocet
Netherlands	Levocetirizine Krka 5 mg filmomhulde tabletten
France	Levocetirizine Krka 5 mg, comprimé pelliculé
Germany	Levocetirizin TAD 5 mg Filmtabletten
Italy	Levocetirizina Krka

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