

CEZERA FILM-COATED TABLETS

Levocetirizine dihydrochloride (5 mg)

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What *Cezera* is used for

Symptomatic treatment of allergic rhinitis (inflammation of the inside of the nose caused by an allergen) including persistent allergic rhinitis and chronic idiopathic urticaria (a raised, itchy rash that appears on the skin, with no obvious cause).

How *Cezera* works

Levocetirizine dihydrochloride, the active ingredient of *Cezera*, is an antihistamine. It blocks the effects of a substance called histamine which occurs naturally in the body. Histamine is involved in allergic reaction.

Before you use *Cezera*

When you must not use it

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

Pregnancy and lactation

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.

Before you start to use it

Talk to your doctor or pharmacist before taking *Cezera*.

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

If you have rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose

malabsorption, please inform your doctor before using this medicine.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy from a pharmacy, supermarket or health food shop without a prescription.

How to use *Cezera*

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

How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Cezera tablets are not recommended for children under 6 years of age.

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

If you have impaired kidney function, you may be given a lower dose, according to the severity of your disease.

If you only have impaired liver function you should take the usual prescribed dose.

If you have both impaired liver and kidney function you may be given a lower dose depending on the severity of the kidney disease.

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

When to use it

Use as directed by your doctor or pharmacist.

The tablets should be swallowed whole with water and may be taken with or without food. It is recommended to take the daily dose in one single intake.

How long to use it

Continue taking *Cezera* for as long as your doctor recommends.

If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

If you use too much (overdose)

A substantial overdose may cause drowsiness in adults.

Children may initially show agitation and restlessness followed by drowsiness.

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists that you are taking *Cezera*.

Tell your doctor immediately if you become pregnant while taking this medication.

Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *Cezera* to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Cezera tablets are not recommended for children under 6 years of age.

Taking *Cezera* with alcohol

Caution is advised if *Cezera* is taken at

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the same time as alcohol.

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

Driving and using machines

Some patients being treated with *Cezera* 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.

Cezera contains lactose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

Side effects

Like all medicines, *Cezera* can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Undesirable effects reported in post marketing experience were: weight gain, abnormal liver function tests, palpitation (rapid, fluttering or pounding heart), visual disturbance, dyspnoea (shortness of breath), nausea, angioneurotic edema (swelling of the deep layers of skin), pruritus (itch), skin rash, urticarial (a red, raised itchy rash), hypersensitivity (including anaphylaxis) and hepatitis (inflammation of the liver).

At the first signs of a **hypersensitivity reaction**, stop taking *Cezera* and see your doctor immediately.

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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine, even if you think the problems are not connected with the medicine.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers→Reporting)

Storage and disposal of *Cezera*

Storage

Keep out of the reach and sight of children.

Do not store above 25°C.

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

Disposal

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

What it looks like

The tablets are white, round, biconvex film-coated tablets with bevelled edges.

Ingredients

Active ingredients

The active substance is levocetirizine dihydrochloride. Each film-coated tablet contains 5 mg levocetirizine dihydrochloride.

Inactive ingredients

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.

MAL number:

MAL11030085AZ

Manufacturer

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia.

Product Registration Holder

Pahang Pharmacy Sdn. Bhd. Lot 5979, Jalan Teratai, 5 ½ Miles off Jalan Meru, 41050, Klang, Selangor, MALAYSIA.

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