PATIENT INFORMATION LEAFLET

ELRIZ Syrup 2.5 mg / 5 ml

Levocetirizine hydrochloride Syrup

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What **ELRIZ** is and what it is used for
2. What you need to know before you take **ELRIZ**
3. How to take **ELRIZ**
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1. WHAT ELRIZ IS AND WHAT IT IS USED FOR

Levocetirizine hydrochloride is the active ingredient of ELRIZ.

ELRIZ is an antiallergic medication.

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 ELRIZ

Do not use ELRIZ if you

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

Do not take ELRIZ syrup if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking ELRIZ syrup.

Warnings and precautions

Talk to your doctor before taking ELRIZ, especially if you

- 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.
- If you suffer from epilepsy or are at risk of convulsions, please ask your doctor for advice as use of ELRIZ may cause seizure aggravation.
- If you are scheduled for allergy testing, ask your doctor if you should stop taking ELRIZ for several days before testing. This medicine may affect your allergy test results

Children and adolescents

The use of ELRIZ is not recommended in children less than 2 years

Other medicines and ELRIZ

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

ELRIZ with food, drink and alcohol

Caution is advised if ELRIZ is taken at the same time as alcohol or other agents acting on the brain.

In sensitive patients, the concurrent administration of ELRIZ and alcohol or other agents acting on the brain may cause additional reductions in alertness and impairment of performance.

ELRIZ can be taken with or without food.

Pregnancy, breast-feeding and fertility

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 ELRIZ may experience somnolence / drowsiness, tiredness and exhaustion. Use caution when driving or operating machinery untill you know how this medicine affects you. 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.

3. HOW TO USE ELRIZ

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

Adults and adolescents from the age of 12 years: 10 ml daily

Special dosage instructions for specific populations:

Renal and hepatic impairment

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 have severe impairment of kidney function must not take Elriz.

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.

Elderly patients aged 65 years and above

No adaptation of the dose is necessary in elderly patients, provided their renal function is normal.

Use in children

Children from the age of 6 to 12 years: 10 ml once daily.

Children from the age of 2 to 6 years: 2.5 ml twice daily.

The administration of Elriz to infants and toddlers aged less than 2 years is not recommended.

How and when should you take ELRIZ?

For oral use only.

ELRIZ may be taken with or without food.

How long should you take ELRIZ?

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

If you take more ELRIZ than you should

If you take more ELRIZ than 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 ELRIZ, please tell your doctor who will then decide what action should be taken.

If you forget to take ELRIZ

If you forget to take ELRIZ, or if you take a dose lower than that prescribed by your doctor, do not take a double dose to make up for a forgotten dose. Take your next dose at your normal time.

If you stop taking ELRIZ

Stopping treatment should have no negative effects. However, rarely pruritus (intense itching) may occur if you stop taking ELRIZ, even if those symptoms were not present before treatment initiation.

The symptoms may resolve spontaneously. In some cases, the symptoms may be intense and may require treatment to be restarted. The symptoms should resolve when the treatment is restarted.

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: may affect up to 1 in 10 people

Dry mouth, headache, tiredness and somnolence/drowsiness

Uncommon: 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, oculogyration (eyes having uncontrolled circular movements), 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, nightmare, hepatitis, abnormal liver function, vomiting, increased appetite, nausea and diarrhoea have also been reported. Pruritus (intense itching) upon discontinuation.

At the first signs of a hypersensitivity reaction, stop taking ELRIZ and tell your doctor. 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly: Website: www.zuventus.co.in and click the tab “Safety Reporting” located on the top right end of the home page.

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

You can also report the side effect with the help of your treating physician.

5. HOW TO STORE ELRIZ

- Store in a cool & dark place.
- Keep out of reach of children
- Do not use this medicine after the expiry date which is stated on the blister and the carton after “EXP”. The expiry date refers to the last day of that month.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What ELRIZ syrup contains

Each 5 ml contains:
Levocetirizine Hydrochloride IP…….. 2.5 mg
Excipients ……..q.s.
In a flavoured syrup base

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