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Package leaflet: Information for the patient

## Levocetirizine dihydrochloride 5 mg film coated tablets

**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.

### What is in this leaflet

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

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

Levocetirizine dihydrochloride is the active ingredient of Levocetirizine dihydrochloride 5 mg film-coated tablets. Throughout the PIL this product will be referred to as 'Levocetirizine'.

Levocetirizine 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 Levocetirizine

#### Do not take Levocetirizine:

- if you are allergic to levocetirizine dihydrochloride or to 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.

The use of Levocetirizine is not recommended in children less than 6 years since the film-coated tablets do not allow for 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

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

### Levocetirizine with food, drink and alcohol

Caution is advised if Levocetirizine is taken at 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.

### 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 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.

### 3. How to take Levocetirizine dihydrochloride 5mg film coated tablets

Always take this medicine exactly as your doctor or pharmacist 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.

Patients with impaired kidney function may be given a lower dose according to the severity of their kidney disease. 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.

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

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

### If you take more Levocetirizine than you should

A substantial overdose may cause somnolence in adults. Children may initially show excitation and restlessness followed by somnolence.

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

### If you forget to take Levocetirizine

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

Stopping the treatment with Levocetirizine earlier than foreseen should have no detrimental effects,



in the sense that the symptoms of the disease should just progressively reappear with a severity not higher than the one experienced prior to treatment with Levocetirizine.

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 1 to 10 users in 100), mainly mild to moderate side effects such as dry mouth, headache, tiredness and somnolence/drowsiness have been reported.

Uncommon (may affect 1 to 10 users in 1,000) side effects such as exhaustion and abdominal pain have been observed.

Other side effects of not known frequency (frequency cannot be estimated from the available data) 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, aggressive or agitated behaviour, hallucination, depression, insomnia, recurring thoughts of or preoccupation with suicide, hepatitis, abnormal liver function, vomiting, increased appetite and nausea, have also been reported.

At the first signs of a hypersensitivity reaction, stop taking Levocetirizine 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.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

**Some people may have side-effects when taking this medicine. If you have any unwanted side-effects you should seek advice from your doctor, pharmacist or other healthcare professional. Also you can help to make sure that medicines remain as safe as possible by reporting any unwanted side-effects via the internet at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) alternatively you can call Freephone 0808 100 3352 (available between 10am-2pm Monday – Friday) or fill in a paper form available from your local pharmacy.**

#### 5. How to store Levocetirizine

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 medicinal product 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 medicines you no longer use. These measures will help protect the environment.

#### 6. Contents of the pack and other information What Levocetirizine contains

- The active substance is levocetirizine dihydrochloride. Each film-coated tablet contains 5 mg levocetirizine dihydrochloride.
- The other ingredients are: Croscarmellose Sodium (E468), Cellulose, Microcrystalline (M102) (E460), Silica, colloidal anhydrous (E551), Magnesium Stearate (E572), Opadry white (03K58884) (containing Hypromellose 6 cps (E464), Titanium Dioxide (E171) and Triacetin (E1518)).

#### What Levocetirizine looks like and the contents of the pack

Levocetirizine 5 mg film-coated tablets are white to off-white, oval film-coated tablets, 2.90 mm to 3.50 mm thick, 7.8 mm to 8.2 mm long and 4.3 mm to 4.7 mm wide, with plain on both sides.

They are supplied in:  
OPA/Al/PVC-Al blisters, packed in carton box.

Pack sizes:  
7, 10, 14, 20, 21, 28, 30, 40, 50, 60, 70, 90 and 100 film-coated tablets

Not all pack sizes may be marketed.

#### Marketing Authorisation Holder and Manufacturer

MA Holder: Strandhaven Ltd t/a Somex Pharma  
High Road, Seven Kings, Ilford, Essex IG3 8BS

Manufacturer: Strandhaven Ltd t/a Somex Pharma  
High Road, Seven Kings, Ilford, Essex IG3 8RA

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

UK	:	Levocetirizine dihydrochloride 5 mg film coated tablets
Portugal	:	Levocetirizina Fair-Med
Germany	:	Levocetirizin Fairmed 5 mg Filmtabletten
Malta	:	Levocetirizine dihydrochloride Fair-Med 5 mg film-coated tablets
Poland	:	Levocetirizine dihydrochloride Fair-Med

This leaflet was last revised in 05/2020