

**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.

**What is in this leaflet**

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

**1. What Levocetirizine dihydrochloride is and what it is used for**

Levocetirizine is an anti-allergic agent. It is used to treat symptoms associated with allergic conditions, such as:

- hay fever
- year round allergies such as dust or pet allergies
- chronic allergic rhinitis (including persistent allergic rhinitis)
- nettle rash (urticaria)

**2. What you need to know before you take Levocetirizine dihydrochloride**

**Do not take Levocetirizine dihydrochloride if**

- you are allergic to levocetirizine or to other antihistamines (eg. Cetirizine hydroxyzine) or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from **severe kidney failure** (severe renal failure with creatinine clearance below 10ml/min)

**Warning and precautions**

Talk to your doctor or pharmacist before taking Levocetirizine dihydrochloride

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

**Other medicines and Levocetirizine dihydrochloride**

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

Other medicines may be affected by levocetirizine. They, in turn, may affect how well levocetirizine works.

### **Levocetirizine dihydrochloride with alcohol**

You should be cautious if you take levocetirizine at the same time as alcohol as it may cause a reduction in alertness and affect your performance.

### **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.

#### Pregnancy

Your doctor may advise you to take levocetirizine during pregnancy, if necessary.

#### Breast-feeding

Levocetirizine is not recommended for use while breast-feeding as it may pass into your breast milk. Do not take this medicine if you are breast-feeding, unless advised by your doctor.

### **Driving and using machines**

Studies in healthy people have shown no effect on the ability to drive or use machines. However in some patients levocetirizine may cause sleepiness/drowsiness, tiredness and exhaustion. Use caution when driving or operating machinery until you know this medicine affects you.

### **Levocetirizine dihydrochloride contains lactose**

These tablets contain 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 dihydrochloride**

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

The recommended dose for adults and children aged 6 years and over is **one tablet daily**. Levocetirizine tablets are not recommended for children under 6 years of age.

### **Special dosage instructions for specific populations:**

If you suffer from mild to moderate **kidney failure**, your doctor may prescribe a lower dose according to the severity of your kidney disease.

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.

No change of the dose is necessary in elderly, provided their kidney function is normal.

#### **Use in children and adolescents**

Levocetirizine tablets are not recommended in children less than 6 years since the tablets cannot be broken to provide the correct dose. For children aged 2 to 6 years it is recommended to use a formulation of levocetirizine designed for children.

In children suffering from decreased kidney function the dose will be chosen on the basis of kidney function and body weight; the dose will be determined by your doctor.

#### **If you take more Levocetirizine dihydrochloride than you should**

If you have taken more Levocetirizine dihydrochloride than you should, you may experience the following symptoms: confusion, diarrhoea, dizziness, fatigue, headache, feeling unwell, dilation of the pupils, itching, restlessness, drowsiness, sleepiness, fast heart beat, shaking and difficulty passing urine. Contact your doctor or pharmacist immediately. They may empty your stomach or can take other measures to alleviate the symptoms.

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

#### **If you forget to take Levocetirizine dihydrochloride**

Do not take a double dose to make up for a forgotten dose. Skip the missed dose and take the next tablet at the usual time.

#### **If you stop taking Levocetirizine dihydrochloride**

If you stop the treatment with levocetirizine earlier than foreseen this should not cause any side effects. The symptoms you took levocetirizine for, may reappear however they should not be any worse than they were prior to the 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.

**Tell your doctor immediately or contact the casualty department at your nearest hospital, if you get the following serious side effects:**

Not known (frequency cannot be estimated from the available data)

- Allergic reaction like swelling of the mouth, face and/or throat or swallowing difficulties together with hives (angioedema), breathing difficulties or a sudden fall in blood pressure leading to collapse or shock, which may be fatal.
- Seizures
- Recurring thoughts of, or preoccupation with, suicide

Other side effects are:

Common (may affect up to 1 in 10 people):

- Dry mouth
- Headache
- Tiredness
- Somnolence/downiness

Uncommon (may affect up to 1 in 100 people):

- Exhaustion
- Abdominal pain

Not known (frequency cannot be estimated from the available data):

- Aggression
- Agitation
- Visual disturbances
- Palpitations
- Nausea
- Diarrhoea
- Inflammation of the liver
- Pruritus (itchiness)
- Rash
- Hives
- Muscle pain
- Joint pain
- Weight increase
- Abnormal liver function tests
- Increased heart rate
- Pins and needles
- Dizziness
- Fainting
- Tremor
- Dysgeusia (distortion of the sense of taste)
- Blurred vision

- Painful or difficult urination
- Inability to completely empty the bladder
- Skin eruption
- Shortness of breath
- Hallucination
- Depression
- Insomnia
- Vomiting
- Oedema
- Increased appetite.

### **Additional side effects (in children)**

Common (may affect up to 1 in 10 people):

- Diarrhoea
- Constipation
- Difficulty in sleeping

### **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 Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine

## **5. How to store Levocetirizine dihydrochloride**

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 packaging after 'EXP'. The first two digits indicate the month and the last four digits indicate the year.

The expiry date refers to the last day of that month.

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

Do not throw away any medicine 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 dihydrochloride contains**

- The active substance is levocetirizine. Each tablet contains 5 mg of levocetirizine dihydrochloride equivalent to 4.2 mg of levocetirizine.

- The other ingredients are microcrystalline cellulose, lactose monohydrate, magnesium stearate (core) and hypromellose (E464), titanium dioxide (E171), and macrogol 400 (coating).

**What Levocetirizine dihydrochloride looks like and contents of the pack**

The film-coated tablets are white to off-white, oval, biconvex film-coated tablets, marked with 'L9CZ' on one side and '5' on the other side.

They are supplied in blister packs of 7, 10, 14, 15, 20, 21, 28, 30, 40, 50, 56, 60, 70, 90, 100, 112 or 120 tablets per box or in unit dose blisters of 30 per box.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

*Marketing Authorisation Holder:* Mylan, Potters Bar, Hertfordshire, EN6 1TL, UK

*Manufacturers:*

- Synthon BV, Microweg 22, 6545 CM Nijmegen, The Netherlands
- Synthon Hispania S.L., Castelló 1, Polígono Las Salinas, 08830, Sant Boi de Llobregat, Spain

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

France - Lévocétirizine MYLAN 5 mg, comprimé pelliculé.

The Netherlands - Levocetirizine diHCl Mylan 5 mg tabletten

United Kingdom - Levocetirizine dihydrochloride 5 mg film-coated tablets

**This leaflet was last revised in 07/2016**