

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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

#### **1. What Rinozal 5 mg is and what it is used for**

The active substance of Rinozal 5 mg is levocetirizine dihydrochloride, which is an anti allergic agent. It is used to treat symptoms associated with allergic conditions, such as:

- chronic nettle rash

#### **2. What you need to know before you take Rinozal 5 mg**

##### **DO NOT take Rinozal 5 mg**

- If you are allergic to levocetirizine, any other related substance, or any of the other ingredients of this medicine (listed in section 6).
- If you suffer from severe kidney failure (less than 10 ml/min creatinine clearance).

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Rinozal 5 mg.

- 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 Levocetirizine dihydrochloride 5 mg may cause seizure aggravation.
- If you are scheduled for allergy testing, ask your doctor if you should stop taking Levocetirizine dihydrochloride 5 mg for several days before testing. This medicine may affect your allergy test results.
- If you suffer from kidney failure. You may require a lower dosage and should discuss your situation with your doctor.

#### **Children**

The use of Rinozal 5 mg is not recommended in children less than 6 years since the film-coated tablets do not allow for dose adaptation.

#### **Other medicines and Rinozal 5 mg**

Other medicines may be affected by Rinozal 5 mg. They, in turn, may affect how well Rinozal 5 mg works.

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

#### **Rinozal 5 mg with food, drink and alcohol**

Rinozal 5 mg may be taken with or without food.

You should be cautious if you take Rinozal 5 mg at the same time as **alcohol**. In sensitive patients the effect of alcohol may be increased or different than expected.

#### **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**

In some patients Rinozal 5 mg may cause drowsiness, tiredness and exhaustion. If you experience any of these symptoms, then do not drive or operate any machines.

#### **Rinozal 5 mg 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 Rinozal 5 mg**

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

You should swallow the tablet **whole** with water or another liquid.

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

#### **Use in children**

Children under 6 years of age should not take Rinozal 5 mg.

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

The duration of treatment depends on the type, duration and course of the complaints. Your doctor or pharmacist will advise you on this.

#### **If you take more Rinozal 5 mg than you should**

If you have taken more Rinozal 5 mg 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 heartbeat, 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 forget to take Rinozal 5 mg**

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 Rinozal 5 mg**

Stopping treatment should have no negative effects. However, rarely pruritus (intense itching) may occur if you stop taking Levocetirizine dihydrochloride 5 mg, 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, 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, diarrhoea and oculogyration (eyes having uncontrolled circular movements) have also been reported. Pruritus (intense itching) upon discontinuation.

At the first signs of a **hypersensitivity reaction**, stop taking Levocetirizine dihydrochloride 5 mg 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 via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Rinozal 5 mg**

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 to protect from moisture.

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 Rinozal 5 mg contains**

- The active substance is levocetirizine (as dihydrochloride). 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 Rinozal 5 mg looks like and contents of the pack**

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

They are supplied in blister packs of 10, 14, 20, 28, 40, 50, 60, 80 or 100 tablets per box and unit dose blisters containing: 30 x 1 tablets.

Not all pack sizes may be marketed.

**Marketing authorisation holder and manufacturer**

*Marketing authorisation holder:*

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

*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

LAMP SAN PROSPERO S.p.A., Via della Pace 25/A, 41030 San Prospero (Modena), Italy

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

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

Belgium	Levocetirizine EG 5 mg, tabletten
France	Levocetirizine EG 5 mg, comprimé pelliculé
Germany	Levocetirizin STADA 5 mg Filmtabletten
Ireland	Rinozal 5 mg film-coated tablets
Italy	Levocetirizina EG 5 mg compresse con rivestite
Luxembourg	Not yet approved

**This leaflet was last revised in April 2018.**