



## Adihistan 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.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

### What is in this leaflet

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

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

Adihistan contains levocetirizine *dihydrochloride* as active substance.

It belongs to the group of antihistamine products and is used for the treatment of symptoms associated with:

- allergic rhinitis, including chronic allergic rhinitis
- nettle rash (swelling, redness and burning of the skin)

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

#### 2. What you need to know before you take Adihistan

##### Do not take Adihistan:

- if you are allergic to levocetirizine dihydrochloride, to other antihistamines or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from severe renal impairment (severe kidney failure and creatinine clearance less than 10 ml/min)

### Warnings and precautions

Talk to your doctor if you are unable to empty your bladder properly due to spinal cord injury or enlarged prostate.

Talk to your doctor or pharmacist before using Adihistan.

### Children and adolescents

Adihistan is not recommended in children less than 6 years since the currently available film-coated tablets do not allow dose adaptation.

### Other medicines and Adihistan

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

### Adihistan with food, drink and alcohol

- You should be cautious when you take Adihistan at the same time as alcohol. In sensitive patients the concurrent use of cetirizine or levocetirizine with alcohol or other CNS suppressing effect may affect the central nervous system although racemic cetirizine studies have not shown an enhanced effect of alcohol.
- Tablets should be swallowed whole with some water, and the intake is not influenced by food. The degree of absorption of levocetirizine is not affected by food although the rate of absorption is slightly slowed.

### 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 taking Adihistan may experience somnolence, fatigue and asthenia. If you intend to drive, engage in potentially hazardous activities or operate machinery, we recommend you to wait in order to establish your response to the medicinal product. Clinical studies conducted in healthy individuals demonstrate that levocetirizine at the recommended dosage has no influence on alertness, reactions and the ability to drive

### Adihistan contains lactose as excipient

If your doctor has told you that you have intolerance to some sugars, you should consult him before taking this medicine.

### 3. How to take Adihistan tablets

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

The recommended dose for adults and children over the age of 6 years is 1 film-coated tablet 5 mg tablet daily.

In patients with kidney disease, dose reduction may

be considered according to the severity of the kidney disease.

No dose adjustment is required for patients with liver impairment.

Patients with impaired kidney or liver function may take a lower dose depending on the severity of the kidney disease.

No dose adjustment is required for elderly patients with normal renal function.

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

The recommended dose for children over 6 is 1 film-coated 5 mg tablet daily. Adihistan is not suitable for children under 6 years.

#### Method of administration:

Tablets should be swallowed whole with some water, and may be taken with or without food.

### **If you take more Adihistan than you should**

Significant overdosing may cause sleepiness in adults. In children, agitation and restlessness may occur followed by sleepiness.

In case of overdosing, you should contact immediately your doctor or the nearest emergency unit.

### **If you forget to take Adihistan**

If you forget to take Adihistan or have taken a lower than the prescribed dose, do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time.

### **If you stop taking Adihistan**

If you stop the treatment with levocetirizine earlier than foreseen, this should not cause any side effects except that the symptoms of the disease may reappear progressively, their severity not higher than that before 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.

The adverse drug reactions are classified according to their frequency, and defined as:

- Very common: may affect more than 1 in 10 people
- Common: may affect up to 1 in 10 people
- Uncommon: may affect up to 1 in 100 people
- Rare: may affect up to 1 in 1,000 people
- Very rare: may affect up to 1 in 10,000 people
- Not known (cannot be estimated from the available data)

The side effects associated with Adihistan tablets, are mostly mild to moderate, including: dry mouth, headache, tiredness and sleepiness. The uncommon side effects are exhaustion and abdominal pain.

Other side effects have also been reported, such as: palpitations, fits, sensation of tingling of the skin, dizziness, syncope, tremor, changed taste sensation,

vertigo, disorders of movement, vision disturbances, blurred vision, pain or difficulty passing urine, inability to empty the bladder completely, swelling, rash, itching, hives, shortness of breath, weight increase, muscle pain, aggressive or overexcited behaviour, hepatitis, abnormal liver function, increased appetite, nausea. With the first appearance of a hypersensitivity reaction, stop taking Adihistan and inform your doctor. Symptoms of hypersensitivity include: swelling of the mouth, face and/or throat, difficulty breathing or swallowing, tightness in the chest or wheezing, hay fever, sudden drop in the 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 or pharmacist. This includes any possible side effects not listed in this leaflet.

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

### **5. How to store Adihistan tablets**

Keep this medicine out of the sight and reach of children.

Store in the original packaging below 30°C.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

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 Adihistan contains**

- The active substance is Levocetirizine dihydrochloride .

Each tablet contains 5 mg Levocetirizine dihydrochloride

- The other ingredients (excipients) are: Cellulose microcrystalline, Lactose monohydrate, Magnesium stearate, Silica colloidal anhydrous, Hypromellose (E464), Hydroxypropyl cellulose, Caprylic capric triglycerides, Titanium dioxide (E171), Macrogol.

#### **What Adihistan looks like and contents of the pack**

White to almost white, oval film-coated tablets with size 9.8 mm x 4.9 mm.

The pack contains blister packs x 15 tablets.

2 blister packs x 15 tablets with a package leaflet in a folding carton box.

#### **Marketing Authorisation Holder and Manufacturer** ADIPHARM EAD

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