

## **Package leaflet: Information for the user**

### **Zitrease Allergy 10 mg film-coated Tablets**

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

#### **1. What Zitrease Allergy is and what it is used for**

Cetirizine dihydrochloride is the active ingredient of Zitrease Allergy 10 mg Tablets.

Zitrease Allergy 10 mg Tablets is an antiallergic medication.

In adults and children aged 6 years and above, Zitrease Allergy 10 mg Tablets are indicated

- for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis
- for the relief of urticaria

#### **2. What you need to know before you take Zitrease Allergy**

##### **Do not take Zitrease Allergy:**

- if you have severe kidney disease requiring dialysis.
- if you are allergic to Cetirizine dihydrochloride, to any of the other ingredients (listed in section 6), to hydroxyzine or to piperazine derivatives (closely related active ingredients of other medicines).

## **Warning and Precautions**

Talk to your doctor or pharmacist before taking Zitrease Allergy

If you are a patient with renal insufficiency, please ask your doctor for advice; if necessary, you will take a lower dose. The new dose will be determined by your doctor.

If you have problems passing urine (like spinal cord problems or prostate or bladder problems) please ask your doctor for advice.

If you are an epileptic patient or a patient at risk of convulsions, you should ask your doctor for advice.

No clinically significant interactions have been observed between alcohol (at the blood level of 0.5 per mille (g/l) corresponding to one glass of wine) and cetirizine used at the recommended doses. However, there are no data available on the safety when higher doses of cetirizine and alcohol are taken together. Therefore, as it is the case with all antihistamines, it is recommended to avoid taking Zitrease Allergy 10 mg tablets with alcohol.

If you are scheduled for allergy testing, ask your doctor if you should stop taking Zitrease Allergy 10 mg Tablets for several days before testing. This medicine may affect your allergy test results.

### **Children**

Do not give this medicine to children below the age of 6 years because the tablet formulation does not allow the necessary dose adjustments.

### **Other medicines and Zitrease Allergy**

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

### **Zitrease Allergy with food and drink**

Food does not affect absorption of Zitrease Allergy.

### **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 for advice before taking this medicine.

Zitrease Allergy should be avoided in pregnant women. Accidental use of the drug by a pregnant woman should not produce any harmful effects on the foetus. Nevertheless, the medicine should only be administered if necessary and after medical advice.

Cetirizine passes into breast milk. A risk of side effects in breastfed infants cannot be excluded. Therefore, you should not take Zitrease Allergy during breast-feeding unless you have contacted a doctor.

### **Driving and using machines**

Clinical studies have produced no evidence of impaired attention, alertness and driving capabilities after taking Zitrease Allergy at the recommended dose. You should closely observe your response to the drug after you have taken Zitrease Allergy if you are intending to drive, engage in potentially hazardous activities or operate machinery. You should not exceed the recommended dose

**Zitrease Allergy film-coated Tablets contains lactose;** if you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per Film-coated tablet, that is to say essentially 'sodium-free'.

### **3. How to take Zitrease Allergy**

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 tablets need to be swallowed with a glass of liquid.  
The tablet can be divided into 2 equal doses.

#### **Adults and adolescents above 12 years old:**

The recommended dose is 10 mg once daily as 1 tablet.  
Other form(s) of this medicine may be more suitable for children, ask your doctor or pharmacist

#### **Use in children between 6 and 12 years old:**

The recommended dose is 5mg twice daily as a half tablet twice daily  
Other form(s) of this medicine may be more suitable for children, ask your doctor or pharmacist

#### **Patients with renal impairment**

Patients with moderate renal impairment are recommended to take 5mg once daily.

If you suffer from severe kidney disease, please contact your doctor or pharmacist who may adjust the dose accordingly.

If your child suffers from kidney disease, please contact your doctor or pharmacist who may adjust the dose according to your child's needs.

If you feel that the effect of Zitrease Allergy is too weak or too strong, please consult your doctor.

**Duration of treatment:**

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

**If you take more Zitrease Allergy than you should**

If you think you have taken an overdose of Zitrease Allergy please inform your doctor.

Your doctor will then decide what measures, if any, should be taken.

After an overdose, the side effects described below may occur with increased intensity. Adverse effects such as confusion, diarrhoea, dizziness, tiredness, headache, malaise (feeling unwell), dilating of pupil, itching, restlessness, sedation, somnolence (sleepiness), stupor, abnormal rapid heart rate, tremors and urinary track retention (difficulty in completely emptying the bladder) have been reported.

**If you forget to take Zitrease Allergy**

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

**If you stop taking Zitrease Allergy**

Rarely, pruritus (intense itching) and/or urticaria may return if you stop taking Zitrease Allergy.

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 following side effects are rare or very rare but you must stop taking the medicine and speak to your doctor straight away if you notice them:**

- Allergic reactions, including severe reactions and angioedema (serious allergic reaction which causes swelling of the face or throat).

These reactions may start soon after you first take the medicine, or it might start later.

**Common side effects** (may affect up to 1 in 10 patients)

- Somnolence (sleepiness)
- Dizziness, headache
- Pharyngitis (sore throat), rhinitis (runny, stuffy nose) (in children)
- Diarrhea, nausea, dry mouth
- Fatigue

**Uncommon side effects** (may affect up to 1 in 100 patients)

- Agitation
- Paresthesia (abnormal feelings of the skin)
- Abdominal pain
- Pruritus (itchy skin), rash
- Asthenia (extreme fatigue), malaise (feeling unwell)

**Rare side effects** (may affect up to 1 in 1000 patients)

- Allergic reactions, some severe (very rare)
- Depression, hallucination, aggression, confusion, insomnia
- Convulsions
- Tachycardia (heart beating too fast)
- Liver function abnormal
- Urticaria (hives)
- Oedema (swelling)
- Weight increased

**Very rare side effects** ( may affect up to 1 in 10,000 patients)

- Thrombocytopenia (low levels of blood platelets)
- Tics (habit spasm)
- Syncope (fainting), dyskinesia (involuntary movements), dystonia (abnormal prolonged muscular contractions), tremor, dysgeusia (altered taste)
- Blurred vision, accommodation disorder (difficulty focusing), oculogyric crisis (eyes having uncontrolled circular movements)
- Angioedema (serious allergic reaction which causes swelling of the face or throat), fixed drug eruption (drug allergy)
- Abnormal elimination of urine (bed wetting, pain and/or difficulty passing water)

**Not Known frequency of side effects** ( frequency cannot be estimated from the available data)

- Increased appetite
- Suicidal ideation (recurring thoughts of or preoccupation with suicide), nightmare
- Amnesia (memory loss), memory impairment
- Vertigo (sensation of rotation or movement)
- Urinary retention (inability to completely empty the urinary bladder)
- Pruritus (intense itching) and/or urticaria upon discontinuation
- Arthralgia (joint pain), myalgia (muscular pain)
- Acute generalized exanthematous pustulosis (rash with blisters containing pus)
- Hepatitis (inflammation of the liver)

## **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 HPRRA Pharmacovigilance, Website: [www.hpra.ie](http://www.hpra.ie)

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

## **5. How to store Zitrease Allergy**

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

This medicine does not require any special storage conditions.

## **6. Contents of the pack and other information**

### **What Zitrease Allergy contains**

- The active substance is Cetirizine dihydrochloride. One film –coated tablet contains 10 mg of Cetirizine dihydrochloride
- The other ingredients are Lactose Monohydrate, Microcrystalline Cellulose, Maize Starch, Colloidal Anhydrous Silica, Magnesium Stearate, Talc, Hypromellose, Titanium Dioxide (E171), Macrogol 4000 and Sodium Citrate.

### **What Zitrease Allergy looks like and contents of the pack**

White, circular film-coated tablets marked ‘A’ on one side and a break line on the other side.

They come in blister packs of 7, 10, 14, 20, 21, 28, 30 and 100 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Bluefish Pharmaceuticals AB  
P.O. Box 49013  
100 28 Stockholm  
Sweden

### **Manufacturer**

Chanelle Medical Unlimited Company, Loughrea, Co. Galway, Ireland.

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

<b>NAME OF MEMBER STATE</b>	<b>NAME OF MEDICINAL PRODUCT</b>
UK	Cetirizine hydrochloride 10 mg film coated Tablets
Ireland	Zitrease Allergy 10 mg film coated Tablets
Italy	Steinar 10 mg compresse rivestite con film
Malta	ALTACURA ALLERGY
Poland	Cetirizinum US Pharmacia

This leaflet was last revised in