

PACKAGE LEAFLET: INFORMATION FOR THE USER

ALER-Z® 10 mg coated tablets

Cetirizine dihydrochloride

Read all of this leaflet carefully before you start taking this medicine.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist for more information.

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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

1. NAME, PHARMACEUTICAL FORM & PRESENTATION OF THE MEDICINAL PRODUCT

ALER-Z® 10 mg Film-coated tablets packs of 7, 14 and 28.

2. COMPOSITION OF THE MEDICINAL PRODUCT

2.1 Qualitative and quantitative composition in active substance

Each film-coated tablet contains 10 mg Cetirizine dihydrochloride.

2.2 Qualitative composition in excipients

Lactose, Starch, Silica colloidal anhydrous, Talc, Microcrystalline cellulose, Magnesium stearate, Opadry white (Code N° 31F58914) and Purified water

2.3 List of excipients with known effect:

Lactose

3. PHARMACO-THERAPEUTIC CLASS:

ALER-Z® 10 mg coated tablet is an antiallergic drug.

4. THERAPEUTIC INDICATIONS

ALER-Z® 10 mg film-coated tablets are indicated in adults and paediatric patients 6 years and above:

- For the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis.
- For the relief of symptoms of chronic idiopathic urticaria.

Medical advice is recommended for chronic idiopathic urticaria

5. POSOLOGY

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

- **Method of administration**

These instructions should be followed unless your doctor has given you different instructions on how to use ALER-Z[®] 10 mg scored tablet. Follow these instructions, otherwise ALER-Z[®] 10 mg scored tablet may not be fully effective.

The tablets should be swallowed with a drink.

Adults and adolescents over 12 years of age:.

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 5 mg 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 5 mg 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 ALER-Z[®] 10 mg 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.

6. CONTRAINDICATIONS

Do not take ALER-Z[®] 10 mg scored tablets:

- if you have severe kidney disease (severe renal insufficiency with creatinine clearance less than 10 ml / min);
- if you are allergic to cetirizine dihydrochloride or to any of the other ingredients of this medication (see Excipients), hydroxyzine or piperazine derivatives (related substances contained in other medicines).

7. UNDESIRABLE 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.

The frequency of possible side effects listed below is defined using the following convention:

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

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

Rare side effects (may affect up to 1 in 1,000 patients)

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

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

Common side effects

- Somnolence (sleepiness)
- Dizziness, headache
- Pharyngitis, rhinitis (in children)
- Diarrhea, nausea, dry mouth
- Fatigue

Uncommon side effects

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

Rare side effects

- 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

- Thrombocytopenia (low levels of blood platelets)
- Tics (habit spasm)
- Syncope, dyskinesia (involuntary movements), dystonia (abnormal prolonged muscular contractions), tremor, dysgeusia (altered taste)
- Blurred vision, accommodation disorder (difficulty focusing), oculogyration (eyes having uncontrolled circular movements)

- Angioedema (serious allergic reaction which causes swelling of the face or throat), fixed drug eruption
- Abnormal elimination of urine (bed wetting, pain and/or difficulty passing water)

Not known frequency of side effects

- Increased appetite
- Suicidal ideation
- Amnesia, memory impairment
- Vertigo (sensation of rotation or movement)
- Urinary retention (inability to completely empty the urinary bladder)

If you develop any of the side effects listed above, please tell your doctor. At the first signs of allergic reaction, stop taking ALER-Z[®] 10 mg scored tablet. Your doctor will assess the severity and decide what to do if necessary.

Reporting of side effects

The reporting of suspected adverse reactions after authorization of the drug is important. It allows continuous monitoring of the benefit / risk ratio of the drug.

8. WARNING AND PRECAUTIONS

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 ALER-Z[®] 10 mg scored tablet with alcohol.

If you have to undergo tests for the diagnosis of allergy (skin test for example), this medication should be stopped at least 3 days before its realization because it can modify the results. Ask your doctor what to do before performing tests for the diagnosis of allergy.

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.

Metions relating to excipients with known effect.

The use of this medication is not recommended in patients with galactose intolerance, Lapp lactase deficiency or glucose or galactose malabsorption syndrome (rare hereditary diseases).

9. INTERACTIONS**Other medicines and ALER-Z[®] 10 mg**

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

ALER-Z[®] 10 mg with food and drink

Food does not affect absorption of ALER-Z[®] 10 mg.

Interactions with herbal medicines or alternative therapies

Not applicable

10. PREGNANCY AND BREAST-FEEDING

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, as your doctor for advice before taking this medicine.

ALER-Z[®] 10 mg 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. Therefore, you should not take ALER-Z[®] 10 mg during breast-feeding unless you have contacted a doctor.

11. DRIVING AND USING MACHINES

Clinical studies have produced no evidence of impaired attention, alertness and driving capabilities after taking ALER-Z[®] 10 mg at the recommended dose.

You should closely observe your response to the drug after you have taken ALER-Z[®] 10 mg if you are intending to drive, engage in potentially hazardous activities or operate machinery. You should not exceed the recommended dose.

12. IF YOU TAKE MORE ALER-Z[®] 10 mg THAN YOU SHOULD

If you think you have taken an overdose of ALER-Z[®] 10 mg 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, ailing, dilating of

pupil, itching, restlessness, sedation, somnolence, stupor, abnormal rapid heart rate, tremors and urinary retention have been reported.

13. IF YOU FORGET TO TAKE ALER-Z® 10 mg

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

14. IF YOU STOP TAKING ALER-Z® 10 mg

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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Special precautions for storage

Not applicable.

Storage conditions

Keep out of the reach and sight of children.

Do not use after the expiry date which is stated on the carton

Marketing Authorisation Holder and Manufacturer



COOPER PHARMA

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