PACKAGE LEAFLET: Information for the patient

ALCET

Film-coated tablets – 10 mg

(Cetirizine hydrochloride)

Read this leaflet carefully before you start taking this medicine.

This medicine is available without prescription. However, you still need to use Alcet carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 3 days.
- 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.

In this leaflet:

1. WHAT ALCET IS AND WHAT IT IS USED FOR

Cetirizine hydrochloride is the active ingredient of Alcet.

Alcet is an antiallergic medication.

In adults and children aged 6 year and above, Alcet is indicated:

- for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis;
- for the relief of chronic nettle rash (chronic idiopathic urticaria).

2. BEFORE YOU TAKE ALCET

Do not take Alcet:

- if you have a severe renal disease (severe renal failure with creatinine clearance below 10 ml/min);
- if you are known to be hypersensitive to the active substance of Alcet, to any of its excipients (other constituents), to hydroxyzine or to piperazine derivatives (closely related active substances of other medicines).

You should not take Alcet 10 mg tablets*:*

- if you have hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

Take special care with Alcet

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 interactions susceptible to have a noticeable impact have been observed between alcohol (at the blood level of 0.5 per mille corresponding to one glass of wine) and cetirizine used at the recommended doses. However, as it is the case with all antihistamines, it is recommended to avoid concurrent consumption of alcohol.

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.

Allergy testing

If you are scheduled for allergy testing, it is necessary to stop the treatment several days before testing because Alcet may affect your test results.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
Due to the profile of cetirizine, no interactions with other drugs are expected.

Taking Alcet with food and drinks

Food does not affect noticeably the absorption of cetirizine.

Pregnancy and breastfeeding

Ask your doctor for advice before taking any medicine.
As with other drugs, use of Alcet 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 administration of the medicine should be discontinued.
You should not take Alcet during breastfeeding because cetirizine passes into breast milk.

Driving and using machines

If you are intending to drive, engage in potentially hazardous activities or operate machinery, you should closely observe your response to the drug, because in some cases it can cause dizziness. You should not exceed the recommended dose.
If you are a sensitive patient, you may find that the simultaneous use of alcohol or other nervous depressant agents may additionally affect your attention and ability to react.

Important information about some of the excipients of Alcet

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

3. HOW TO TAKE ALCET

These guidelines apply unless your doctor has given you different instructions on how to take Alcet.

Please follow these instructions, otherwise Alcet may not be fully effective.

Tablets need to be swallowed with a glass of liquid.

Adults and adolescents above 12 years old

10 mg (one tablet) once daily.

Children between 6 and 12 years old

5 mg (half tablet) twice daily.

Patients with moderate to severe renal impairment

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

If you feel that the effect of Alcet 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 Alcet than you should

If you think you have taken an overdose of Alcet, 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.

If you forget to take Alcet

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

If you stop taking Alcet

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

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, cetirizine can cause side effects, although not everybody gets them.

The following side effects have been reported in post-marketing experience.

The frequencies are defined as such:

Common: may affect up to 1 in 10 patients,

Uncommon: may affect up to 1 in 100 patients,

Rare: may affect up to 1 in 1000 patients,

Very rare: may affect up to 1 in 10000 patients,

Not known: frequency cannot be estimated from the available data.

Blood and lymphatic disorders:

very rare: thrombocytopenia (low levels of blood platelets).

General system disorders

common: fatigue.

Metabolism and nutrition disorders:

not known: increased appetite.

Cardiac disorders:

rare: tachycardia (heart beating too fast).

Eye disorders:

very rare: accommodation disorder, blurred vision, oculogyration (eyes having uncontrolled circular movements).

Ear and labyrinth disorders:

not known: vertigo (sensation of rotation or movement).

Gastrointestinal disorders:

common: dry mouth, nausea

uncommon: abdominal pain, diarrhoea.

General disorders and administration site conditions:

uncommon: asthenia (extreme fatigue), malaise

rare: oedema (swelling).

Immune system disorders:

rare: allergic reactions, some severe (very rare)

very rare: anaphylactic shock.

Hepatobiliary disorders:

rare: liver function abnormal

not known: hepatitis (inflammation of the liver).

Investigations:

rare: increased weight.

Nervous system disorders:

common: dizziness, headache

uncommon: paresthesia (abnormal feelings of the skin)

rare: convulsions, movements disorders

very rare: syncope, tremor, dysgeusia (altered taste), dystonia (abnormal prolonged muscular contractions)

not known: amnesia (memory loss), memory impairment.

Psychiatric disorders:
common: somnolence
uncommon: agitation
rare: aggression, confusion, depression, hallucinations, insomnia
very rare: tic
not known: suicidal ideation, nightmares.

Renal and urinary disorders:
very rare: abnormal elimination of urine (dysuria, enuresis)
not known: urinary retention.

Respiratory system disorders:
common: pharyngitis, rhinitis.

Skin and subcutaneous tissue disorders:
uncommon: pruritus, rash
rare: urticaria
very rare: oedema, fixed drug eruption
not known: acute generalized exanthematous pustulosis (AGEP) (rashes with blister containing pus), pruritus (intense itching) and/or urticaria upon discontinuation.

Musculoskeletal and connective tissue disorder
not known: arthralgia (joint pain), myalgia (muscular pain).

If you develop one of the side effects described above, please inform your doctor. At the first signs of a hypersensitivity reaction, stop taking Alcet. Your doctor will then assess the severity and decide on any further measures that may be necessary. If you think you have any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE ALCET

Keep out of the sight and reach of children!

Do not use Alcet after the expiry date which is stated on the package.

Store below 25°C!

Keep in the original package.

6. OTHER INFORMATION

What Alcet contains

The active substance is cetirizine hydrochloride.

Each film-coated tablet contains 10 mg cetirizine hydrochloride.

The excipients are: lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, croscarmellose sodium, talc, magnesium stearate, and Opadry® II white consisting of polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc.

Content of the pack

Box with 20 film-coated tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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