

PATIENT INFORMATION LEAFLET

ALLERSET® 10 mg Film Coated Tablets

Oral use

- **Active substance:** Cetirizine dihydrochloride.
Each tablet contains 10 mg cetirizine dihydrochloride.
- **Excipients:** Corn starch, lactose monohydrate, polyvinylpyrrolidone, magnesium stearate, Eudragit E, polyethylene glycol 6000, titanium dioxide, talc.

Read all of this PATIENT INFORMATION LEAFLET carefully before you start taking this medicine, because it contains important information for you.

- *Keep this leaflet because you may need to read it again.*
- *If you have any further questions or are not sure about anything, please ask your doctor or your pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others as it may harm them, even if their symptoms 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.*

In this patient information leaflet:

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1. What ALLERSET® is and what it is used for?

Cetirizine dihydrochloride is the active ingredient of ALLERSET®. ALLERSET® is an antiallergic medication.

In adults and children aged 6 year and above, ALLERSET® 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. What you need to know before you use ALLERSET®

DO NOT USE ALLERSET® if you have any of the following

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

You should not take ALLERSET® 10 mg tablets:

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

Take special care with ALLERSET® if you have any of the following

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 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 normal doses. However, as it is the case with all antihistamines, it is recommended to avoid concurrent consumption of alcohol.

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 ALLERSET® with food and drink

You can take ALLERSET® on an empty or full stomach.

Pregnancy and breast-feeding

Ask your doctor for advice before taking any medicine. As with other drugs, use of ALLERSET® 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 ALLERSET® during breast feeding because cetirizine passes into breast milk.

Driving and using machinery

Clinical studies have produced no evidence of impaired attention, alertness and driving capabilities after taking ALLERSET® at the recommended dose. If you are intending to drive, engage in potentially hazardous activities or operate machinery, you should not exceed the recommended dose. You should closely observe your response to the drug. 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 on some excipients present in ALLERSET®

ALLERSET® contains lactose. If you have been told by your doctor that you have intolerance to some sugars, please contact your doctor before taking this medicinal product.

3. How to use ALLERSET®?

Instructions for proper use and dosage/administration frequency:

These guidelines apply unless your doctor has given you different instructions on how to use ALLERSET®. Please follow these instructions, otherwise ALLERSET® may not be fully effective.

Tablets need to be swallowed with a glass of liquid.

Adults and adolescents above 12 years old:

10 mg once daily as 1 tablet.

Children between 6 and 12 years old: 5 mg twice daily as a 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 ALLERSET® 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 ALLERSET® than you should

If you think you have taken an overdose of ALLERSET® 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 ALLERSET®

Do not take a double dose to make up for forgotten dose. If you stop taking ALLERSET®. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

Following side effects have been reported in post marketing experience. The frequencies are defined as such: (common: 1 patient out of 100 to 1 out of 10, uncommon: 1 out of 1,000 to 1 out of 100, rare: 1 out of 10,000 to 1 out of 1,000, very rare: less than 1 out of 10,000).

- Blood and lymphatic disorders:

very rare: thrombocytopenia (low levels of blood platelets)

- Body as a whole:

common: fatigue

- Cardiac disorders:

rare: tachycardia (heart beating too fast)

- Eye disorders:

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

- Gastro-intestinal disorders:

common: dry mouth, nausea, diarrhoea

uncommon: abdominal pain

- General disorders and administration site conditions:

uncommon: asthenia (extreme fatigue), malaise

rare: oedema (swelling)

- Immune system disorders:

rare: allergic reactions, some severe (very rare)

- Hepatobiliary disorders: rare: liver function abnormal

- Investigations:

rare: weight increased

- Nervous system disorders:

common: dizziness, headache

uncommon: paresthesia (abnormal feelings of the skin)

rare: convulsions, movements disorders

very rare: syncope, tremor, dysgeusia (altered taste)

- Psychiatric disorders:

common: somnolence

uncommon: agitation

rare: aggression, confusion, depression, hallucination, insomnia

very rare: tic

- Renal and urinary disorders:
very rare: abnormal elimination of urine

- Respiratory system disorders:
common: pharyngitis, rhinitis

- Skin and subcutaneous tissue disorders:
uncommon: pruritus, rash rare: urticaria
very rare: oedema, fixed drug eruption

If you develop one of the side effects described above, please inform your doctor. At the first signs of a hypersensitivity reaction, stop taking ALLERSET®. 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.

Reporting side effects

Please inform your doctor, pharmacist or nurse if you get any side effect whether or not included in this leaflet. In addition, please report the side effect that you are experiencing to Turkish Pharmacovigilance Center (TÜFAM) by clicking to the icon "Reporting Drug Side Effects" at www.tick.gov.tr or call the reporting hotline dialing 0 800 314 00 08. By reporting the side effects, you can help provide more information on the safety of this medicine.

5. How to store ALLERSET®?

Keep out of the reach and sight of children. Store at room temperature below 25°C in its container.

Use in compliance with the expiry date.

Do not use ALLERSET® after the expiry date which is stated on the packaging.

6. Further Information

What ALLERSET® contains

- The active substance of ALLERSET® is cetirizine dihydrochloride. One film-coated tablet contains 10 mg cetirizine dihydrochloride.

- The other ingredients are corn starch, lactose monohydrate, polyvinylpyrrolidone, magnesium stearate, Eudragit E, polyethylene glycol 6000, titanium dioxide, talc.

What ALLERSET® looks like and contents of the pack

White or practically white biconvex, round film-coated tablets with sn/10 logo on one side. Presented in 3 different blister packs containing 10, 20 and 30 film-coated tablets.

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This leaflet has been approved on 12/04/2023.