

PATIENT INFORMATION LEAFLET

ALLERSET® 1 mg/ml syrup

For oral use.

- **Drug Substance:** Cetirizine dihydrochloride. Each ml of syrup contains 1 mg cetirizine dihydrochloride.
- **Excipients:** Sorbitol (E420), glycerol, propylene glycol, sodium saccharin, banana extract, sodium acetate, acetic acid, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216) and deionized water.

Read all of this Patient Information Leaflet carefully before you start using this medicine because it contains important information for you.

- *Keep this Patient Information Leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *During the use of this product, tell your doctor that you use this medicinal product.*
- *Strictly follow these Patient Information Leaflet. Do not take **lower or higher** doses than the recommended dose.*

In this Patient Information Leaflet:

1. *What ALLERSET® is and what it is used for?*
2. *What you need to know before you are given ALLERSET*
3. *How to use ALLERSET®?*
4. *Possible side effects*
5. *How to store ALLERSET?*

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

ALLERSET® is presented in amber bottles containing 200 ml syrup with a 5 ml graduated measuring spoon. This is a colorless, almost clear solution.

ALLERSET® syrup is a medication used in the treatment of allergic rhinitis and urticaria (hives).

ALLERSET® is used in:

Adults and children aged 2 years and older:

For the treatment of nasal and ocular symptoms associated with allergic rhinitis.
For the treatment of urticaria (hives).

2. What you need to know before you are given ALLERSET®

Do not use ALLERSET® if you have the following:

- If you have a history of hypersensitivity to the active substance or any of the excipients, including hydroxyzine or piperazine derivatives.
- You have severe renal impairment (creatinine clearance below 10 ml/min, which indicates significant kidney dysfunction).
- You are under 2 years old.

Take special care with ALLERSET® if you have the following:

- If you have kidney failure, consult your doctor. If necessary, your dosage will be reduced. Your doctor will determine the appropriate new dose for you.
- If you have urination problems (such as due to spinal cord issues, prostate, or bladder problems), consult your doctor.
- If you have epilepsy or are at risk of seizures (convulsions), consult your doctor.
- When used at recommended doses, no clinically significant interaction has been observed between ALLERSET® and alcohol (at a blood alcohol level of 0.5 g/L — equivalent to one glass of wine). However, there is no safety data on the use of ALLERSET® with higher doses of alcohol. Therefore, as with other antihistamines, you should avoid alcohol consumption while taking ALLERSET®.
- If you are scheduled to have an allergy test, consult your doctor about whether you need to stop taking ALLERSET® a few days before the test. ALLERSET® may affect the results of allergy testing.
- If any of these warnings apply to you now or in the past, please consult your doctor.

Taking ALLERSET® with food and drink

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

Pregnancy

Consult your doctor or pharmacist before using this medicine.

The use of ALLERSET® should be avoided during pregnancy. Although accidental use of the medicine during pregnancy is not expected to harm the fetus, it is recommended that

ALLERSET® be used during pregnancy only if absolutely necessary and with caution. If you discover that you are pregnant during treatment, consult your doctor immediately.

Breastfeeding

If you are breastfeeding, before using this medicine consult your doctor or pharmacist.

The active substance of ALLERSET® (cetirizine) passes into the breast milk and ALLERSET® is not recommended during lactation.

Driving and using machinery

Objective measurements of driving ability, sleep latency and simulated assembly line performance (Computer-generated and accurate measurement of all variables in the sleep state, used to measure the sedative effect of the drug, representing performance in the real work environment) have not demonstrated any clinically relevant effects at the recommended dose of 10 mg.

Patients intending to drive, engaging in potentially hazardous activities or operating machinery should not exceed the recommended dose and should take their response to the medicinal product into account. In these sensitive patients, concurrent use ALLERSET® with alcohol or other central nervous system depressants may cause reductions in alertness and impairment of performance.

Important information on some excipients present in ALLERSET®

ALLERSET® contains methyl paraben and propyl paraben, which may cause allergic reactions (possibly delayed).

This medicinal product contains less than 1 mmol (23 mg) of sodium per ml; that is to say, it is essentially "sodium-free".

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

Taking with other medicines

ALLERSET® has no known clinically significant interactions with other medications.

However, the concomitant use of ALLERSET® with alcohol or other central nervous system depressants (e.g., benzodiazepines, valproate, topiramate) may lead to decreased alertness and impaired performance.

If you are currently using, or have recently used, any prescription or non-prescription medicines, please inform your doctor or pharmacist.

3. How to use ALLERSET®?**Instructions for proper use and dosage/administration frequency:****Children aged between 2-6 years:**

The recommended dose is 2.5 ml of syrup twice daily (half a spoonful twice a day).

Children aged between 6-12 years:

The recommended dose is 5 ml of syrup twice daily (one full spoonful twice a day).

Adults and children over 12 years of age:

The recommended dose is 10 ml of syrup once daily (two full spoonfuls once a day).

Route and method of administration:

ALLERSET® syrup is for oral use.

Different age groups

Use in children: The use of ALLERSET® Syrup is not recommended in children aged less than 2 years.

In elderly: There is no need to reduce the dose if renal function is normal.

Special usage**Renal / Hepatic Failure:**

If you have renal failure and hepatic failure, your doctor will adjust the dose according to the severity of renal failure.

In children with renal failure, the dose should be individually adjusted by the physician, taking into account the renal function and body weight.

Only those with hepatic failure can take normal prescription doses. Dosage adjustment is recommended for patients with both renal and liver failure.

If you have the impression that the effect of ALLERSET® is too strong or weak, talk with your doctor or pharmacist.

If you use more ALLERSET® than you should

In case of overdose, the side effects listed below may be more severe: confusion, diarrhea, dizziness, fatigue, headache, malaise, dilated pupils, itching, marked agitation with continuous movement, sedation, somnolence (drowsiness), stupor (lethargy), tachycardia (abnormally fast heartbeat), tremor, and urinary retention have been reported.

If you have taken more ALLERSET® than you should, contact a doctor or pharmacist immediately.

If you forget to use ALLERSET®

Continue to take your medicine according to the instructions given by your doctor.

Do not take double dose to make up the dose you have missed.

Effects that may occur if you stop taking ALLERSET®

When you stop taking ALLERSET®, intense itching and/or urticaria (hives) may rarely return.

The duration of treatment with ALLERSET® depends on the clinical symptoms and the individual course of the condition.

Do not discontinue the treatment without your doctor's advice, as this may lead to the recurrence or worsening of your symptoms.

The decision to stop treatment with ALLERSET® should be made by your doctor.

Possible side effects

Like all medicines, ALLERSET® may cause side effects in patients sensitive to its ingredients.

If any of the following reactions happen, stop taking ALLERSET® and tell your doctor immediately or contact the casualty department at your nearest hospital:

Serious allergic reactions, including angioedema (swelling of the face or throat), are included in the serious side effects that may require emergency medical intervention or hospitalization. These reactions can occur immediately or later after taking the medication. If you experience any of the reactions below, it indicates a serious allergic reaction, and you may need urgent medical help.

Side Effects are categorized by frequency:

- Very common: May affect at least 1 in 10 patients.
- Common: May affect 1 in 100 patients, but less than 1 in 10.
- Uncommon: May affect 1 in 1,000 patients, but less than 1 in 100.
- Rare: May affect 1 in 10,000 patients, but less than 1 in 1,000.
- Very rare: May affect fewer than 1 in 10,000 patients.
- Unknown: Based on the available data, these cannot be estimated.

Common side effects:

- Somnolence (drowsiness)
- Dizziness
- Headache
- Pharyngitis (throat inflammation)
- Rhinitis (cold symptoms) (in children)
- Diarrhea
- Nausea
- Dry mouth
- Weakness

Uncommon side effects:

- Agitation (restlessness)
- Paresthesia (temporary loss of sensation, numbness/tingling)
- Abdominal pain
- Itching
- Rash
- Asthenia (fatigue)
- Aches and pains

Rare side effects:

- Allergic reactions (some may be severe)
- Depression
- Hallucinations (seeing/hearing things that are not real)
- Aggression
- Confusion (mental disorientation)
- Insomnia (difficulty sleeping)
- Seizures (convulsions)
- Tachycardia (fast heart rate)
- Liver function abnormalities
- Urticaria (hives)
- Swelling
- Weight gain

Very rare side effects:

- Thrombocytopenia (decreased platelets, cells responsible for blood clotting)
- Tics
- Syncope (fainting)
- Dyskinesia (difficulty controlling voluntary movements)
- Dystonia (involuntary muscle spasms, twitching)
- Tremors
- Taste disturbances
- Blurred vision
- Accommodation disorders (issues with eye focus)
- Oculogyric crisis (involuntary eye movements)
- Angioedema (swelling of face, lips, mouth, throat)
- Fixed drug eruption (rash)

- Enuresis (involuntary urination)
- Dysuria (painful urination)

Unknown side effects:

- Increased appetite
- Suicidal thoughts
- Nightmares
- Forgetfulness
- Memory issues
- Vertigo (dizziness due to balance problems)
- Urinary retention (difficulty urinating)
- Intense itching and/or urticaria (hives) after discontinuation of treatment
- Joint pain
- Acute generalized exanthematous pustulosis (rash with inflammatory blisters)
- Hepatitis (liver inflammation)

If you experience any of the above side effects or if symptoms worsen, contact your doctor or pharmacist.

Reporting side effects

Talk to your doctor, pharmacist or nurse if you experience any side effects listed or not listed in this leaflet. Also reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

4. How to store ALLERSET?

Store ALLERSET® in original packaging and keep out of the reach and sight of children. Store at room temperature below 25°C.

Use in compliance with the expiry date.

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

Do not throw away drugs that have expired or are not used! Deliver to the collection system determined by the Ministry of Environment and Urbanism.

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This leaflet has been approved <{DD month YYYY}>. [To be completed nationally]