

PATIENT INFORMATION LEAFLET

SANTALLERT® oral drop 10 mg/ml

For oral use.

- **Active ingredient:**
Each 1 ml of the oral drop contains 10 mg of cetirizine dihydrochloride.
- **Excipients:** Glycerine, propylene glycol, sodium saccharine, methyl paraben (E218), propyl paraben (E216), sodium acetate, acetic acid and deionized water.

Read All of THIS PACKAGE INFORMATION LEAFLET carefully before you start taking this medicine because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *Tell your doctor that you are taking this medicine, when you seek medical help from a doctor or medical facility.*
- *Follow these instructions carefully. Do not take **higher or lower** doses than recommended.*

In this leaflet:

- 1. What SANTALLERT® is and what it is used for**
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1. What SANTALLERT® is and what it is used for?

SANTALLERT® is provided in honey colored bottles containing 20 ml of oral drop together with a plastic dropper. The solution is colorless, almost clear.

SANTALLERT® is used for the treatment of allergic rhinitis, chronic urticaria of unknown origin and pruritus.

In adults and children aged 2 or over, SANTALLERT® Oral drop is used for the treatment of the following;

- The eye and nose symptoms of allergic rhinitis, chronic idiopathic urticaria (chronic urticaria of unknown origin), and for the symptoms of pruritus.

2. Before you take SANTALLERT® DO NOT TAKE

- If you have a history of hypersensitivity to the active ingredient of SANTALLERT® or any of its excipients, as well as to hydroxyzine or piperazine derivatives.
- If you have severe renal impairment (renal impairment associated with a creatinine [a substance used to monitor kidney functions] clearance below 10 ml/min)
- Do not use SANTALLERT® in children under 2 years of age

CAUTION SHOULD BE EXERCISED in the following conditions when taking SANTALLERT®

- If you have kidney impairment, consult your doctor. If necessary, the dose of your medicine will be reduced. Your doctor will determine the new dose you should take.
- If you have problems with urination (spinal cord problems or prostate or bladder problems), consult your doctor.
- Consult your doctor if you have epilepsy or if you are at risk of convulsions (seizures, convulsions).
- No clinically significant interaction has been observed when SANTALLERT® is taken with alcohol at recommended doses (0.5 g/l blood level - equivalent to one glass of wine). However, there are no data on the safety of SANTALLERT® and alcohol at higher doses. Therefore, as with other antihistamines, you should avoid alcohol with SANTALLERT®.
- If you need to have an allergy test, ask your doctor whether you should stop treatment with SANTALLERT® a few days before the test. SANTALLERT® may affect the results of an allergy test.

If these precautions apply to you or have ever applied to you, please consult with your doctor.

Effect of food and drinks with SANTALLERT®

SANTALLERT® may be taken with or without food.

Pregnancy

- *Please contact your doctor or pharmacist before taking this medicine*
- The use of SANTALLERT® should be avoided in pregnant women. Although accidental use of the drug during pregnancy has no harmful effects on the foetus, SANTALLERT® should be used with caution during pregnancy only when absolutely necessary.
- *If you become pregnant during treatment with this medicine, immediately contact your doctor or pharmacist*

Lactation

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

Since the active ingredient of SANTALLERT® (cetirizine) is secreted into the human breast milk, lactating mothers are not recommended to use SANTALLERT®.

Driving and using machines

Objective measurements of driving ability, sleep latency and simulated assembly line performance (a computer based measurement used for assessing the sedative effects of medications and representing the real-life workplace performance that is sensitive to all parameters during sleep) 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 medicine into account. In these sensitive patients, concurrent use of SANTALLERT® with alcohol or other central nervous system depressants may cause additional reductions in alertness and impairment of performance.

Important information about some of the ingredients of SANTALLERT®:

- SANTALLERT® contains methyl paraben and propyl paraben and may cause allergic reactions (possibly delayed).
- Since SANTALLERT® contains 350 mg propylene glycol in 1 ml, it may cause alcohol-like symptoms.
- SANTALLERT® contains less than 10 g glycerol in 1 ml. No glycerol-related adverse effects are expected due to its dose.
- This medicinal product contains less than 1 mmol (23 mg) sodium per ml, i.e. it is essentially 'sodium-free'.

Use with other medications

SANTALLERT® has no known clinically relevant interactions with other medicines.

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

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

3. How to use SANTALLERT®?

Instructions for appropriate use and dose/administration frequency:

Children aged between 2 and 6 years: The recommended dose is 2.5 mg twice daily (5 drops twice daily).

Children aged between 6 and 12 years: The recommended dose is 5 mg twice daily (10 drops twice daily).

In adults and children over 12 years of age: The recommended dose is 10 mg twice daily (20 drops twice daily).

SANTALLERT® should be taken by dropping on a spoon or diluted in a small amount of liquid. If dilution is to be made, especially during administration to children, the volume of water to be added to the drops should be adjusted according to the amount of water that the patient can swallow. The diluted solution should be taken immediately. When counting drops, the bottle should be held vertically (upside down). When there is no drop flow and therefore the correct amount of drops cannot be given, turn the bottle upright and then continue counting the drops by holding it upside down again.

Route and method of administration:

SANTALLERT® oral drop is for oral use.

Age groups:

Use in children: Not recommended for use in children under 2 years of age.

Use in elderly: No dose reductions are required if renal functions are normal.

Special precautions for use:**Renal/Hepatic Impairment:**

If you have renal and hepatic impairment, the dose is adjusted by your doctor depending on the severity of renal impairment.

In children with renal impairment, the dose should be adjusted individually by your doctor depending on the renal functions and body weight.

Patients with hepatic impairment only may receive the prescribed dose. In patients with both renal and hepatic impairment, dose adjustment is recommended.

If you have an impression that the effect of SANTALLERT® is weaker or stronger than expected, tell your doctor or pharmacist.

If you take more SANTALLERT® than you should

In overdose, the following side effects may be more severe. Side effects such as confusion, diarrhoea, drowsiness, weakness, headache, malaise, dilated pupils, itching, excessive restlessness characterised by non-stop movement, sedation, somnolence, stupor, tachycardia (abnormally fast heartbeat), tremor and urinary retention have been reported.

If you have taken more SANTALLERT® than you should, contact your doctor or pharmacist.

If you forget to take SANTALLERT®

Continue taking the medication as prescribed by your doctor.

Do not take double dose to make up for the missing dose.

Effects that may be observed when treatment with SANTALLERT® is stopped

The duration of treatment with SANTALLERT® depends on the clinical symptoms and individual course of the disease.

The duration of treatment with SANTALLERT® depends on the clinical symptoms and the individual course of the disease. Do not discontinue treatment without the advice of your doctor, as this may cause the symptoms to reappear or worsen. Your doctor should decide whether to discontinue treatment with SANTALLERT®.

4. What are possible side effects?

As with all medications, side effects may occur in individuals who are sensitive to any ingredient of SANTALLERT®

If any of the following occurs, stop taking SANTALLERT® and immediately contact your doctor or seek urgent medical attention:

Allergic reactions, severe reactions and angioedema (a severe allergic reaction causing swelling of the face or throat)

These are all very serious side effects.

If you have any of these, you are seriously allergic to SANTALLERT®. You may need urgent medical attention or hospitalisation.

These reactions may start immediately or later after taking the medicine. The side effects mentioned above are rare or very rare.

The side effects are listed as shown in the following categories

Very common: It may occur in at least 1 in 10 patients.

Common: Less than 1 in 10 patients, but more than 1 in 100 patients.

Uncommon: Less than one in 100 patients, but more than one in 1000 patients.

Rare: Less than one in 1000 patients, but more than one in 10.000 patients.

Very rare : It may occur in less than 1 in 10,000 patients.

Unknown : Cannot be estimated based on available data

Common:

Somnolence (drowsiness) Feeling dizzy

Headache

Pharyngitis (inflammation of the pharynx)

Rhinitis (catarrh) (in children)

Diarrhoea (diarrhoea)

Nausea

Dry mouth

Fatigue

Uncommon:

Agitation (excessive restlessness)

Paresthesia (temporary absence of sensation, numbness / tingling)

Abdominal pain

Itching

Rash

Asthenia (fatigue)

Brokenness

Rare:

Allergic reactions, some severe (very rare)

Depression

Hallucination (hallucination, seeing/hearing things that are not real)

Aggression

Confusion (confusion of mind)

Insomnia

Convulsions (involuntary muscle contractions, seizures, convulsions)

Tachycardia (the number of heart beats per minute - the pulse - is above normal)

Abnormal liver function (increased transaminase, alkaline phosphatase, gamma-GT and bilirubin)

Urticaria (hives)

Edema

Weight gain

Very rare:

Thrombocytopenia [decreased number of platelets (blood clotting cells) in the blood]
Tik
Syncope (fainting)
Dyskinesia (difficulty in voluntary movement)
Dystonia (involuntary twitching, spasms or movements of the muscles)
Trembling
Taste disturbance
Blurred vision
Disorder of accommodation (eye maladjustment)
Oculogyration (involuntary movement of the eyeball in any direction)
Angio-oedema (swelling of the hands, feet, wrists, face, lips or swelling of the mouth or throat, especially if it makes swallowing or breathing difficult)
Fixed drug eruption (rash)
Enuresis (urinary incontinence)
Dysuria (painful urination)

Unknown:

Increased appetite
Suicidal ideation (recurrent suicidal thoughts or suicidal anxiety)
Nightmares
Forgetfulness
Memory impairment
Dizziness caused by impaired balance (vertigo)
Inability to urinate, difficulty urinating
Intense itching and/or urticaria (hives) (when treatment is stopped)
Joint pain
Rash accompanied by inflamed blisters (acute generalised exanthematous pustulosis)
Hepatitis (inflammation of the liver)

If you experience any side effects not listed in this leaflet, please inform your doctor or pharmacist.

Reporting of 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.

5. How to store SANTALLERT®

SANTALLERT® should be kept out of the sight and reach of children in its original packing. Store in room temperature below 30°C

Do not use after the expiry date.

Do not use SANTALLERT® after the expiry date printed on the package.

Do not dispose of expired or unused medication in the trash! Dispose of them according to the collection system established by the Ministry of Environment and Urbanization

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