

**PATIENT INFORMATION LEAFLET****ROLINOZ 10 mg/mL Oral Drops****Taken orally**

**Active substance:** Cetirizine dihydrochloride (Each 1 ml contains 10 mg of cetirizine dihydrochloride.)

**Excipients:** Glycerol, propylene glycol, saccharin sodium, methyl parahydroxybenzoate, propyl parahydroxybenzoate, sodium acetate trihydrate, glacial acetic acid and purified water.

**Read all of this LEAFLET carefully before you start taking this medicine, it includes special 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. Do not pass it on to others.*
- *If you go to doctor or hospital at the time of using this medicine, please tell your doctor.*
- *Please follow the instructions exactly. Do not use another **high or low** doses out of recommended.*

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## **1. What ROLINOZ is and what it is used for**

Rolinoz 10 mg/mL Oral Drops is presented in 20 mL nominal capacity amber coloured type III glass bottles which is closed by white child-proof PEHD/PELD cap with dropper and in a cardboard box with patient information leaflet.

ROLINOZ Oral Drops is a drug used in the treatment of allergic rhinitis, chronic hives of unknown cause and itching.

ROLINOZ;

2 years and older infants, children and adults;

- It is used in the treatment of nasal and ocular symptoms of allergic rhinitis, chronic idiopathic urticaria (chronic hives of unknown cause) and itching symptoms.

## **2. Before you take ROLINOZ**

### **Do not take ROLINOZ in the following conditions**

- If you have a history of hypersensitivity to the active substance of ROLINOZ or any of the excipients, hydroxyzine or piperazine derivatives,
- Do not use this medicine if you have severe renal impairment (renal impairment where your creatinine clearance (clearing of creatinine, a substance used to monitor renal function, from the blood through the kidneys) is below 10 ml/min.)
- Do not use ROLINOZ in children under 2 years of age.

### **USE ROLINOZ CAREFULLY in the following cases**

- Be careful if you take ROLINOZ with alcohol.
- Consult your doctor if you have urination problems (spinal cord problems or prostate or bladder problems).
- If you need to have an allergy test, ask your doctor if you can stop the treatment with ROLINOZ a few days before the test. ROLINOZ may affect the results of the allergy test

If these warnings apply to you or even if any time in the past, please consult your doctor.

**Taking ROLINOZ with food and drink:**

You can take ROLINOZ on an empty stomach or a full stomach.

**Pregnancy**

*Consult your doctor or pharmacist before administration this medicine.*

- There are very few clinical data available on the use of ROLINOZ in pregnant women. Although animal studies have not shown any harmful effects, it is recommended that ROLINOZ be used during pregnancy only when absolutely necessary and with caution.
- *If you notice that you are pregnant during treatment, consult your doctor immediately.*

**Breast feeding**

*Consult your doctor or pharmacist before administration this medicine*

Since the active substance (cetirizine) in the content of ROLINOZ passes into breast milk, it is not recommended for nursing mothers to use ROLINOZ.

**Driving and using machines**

At the recommended 10 mg dose, cetirizine did not have a clinically significant effect on the efficiency of driving ability, falling asleep, and simulated assembly line (computer-driven measurement sensitive to all variables in sleep, representing performance in a real work environment, used to measure the drowsiness/drowsiness effect of the drug).

Patients planning to drive, operate potentially hazardous jobs, or operate machinery should not exceed the recommended dose and should consider their response to the drug. In such susceptible patients, concomitant use of ROLINOZ with alcohol or other central nervous system depressants (suppressants) may lead to decreased alertness and impaired performance.

**Important information about some excipients in the content of ROLINOZ**

Since ROLINOZ contains methyl parahydroxybenzoate and propyl parahydroxybenzoate, it may cause allergic reactions (possibly delayed).

ROLINOZ may cause alcohol-like symptoms due to the propylene glycol it contains.

### **Concomitant use with other medicines**

There are no known, clinically significant interactions of ROLINOZ with other drugs.

*Please inform your doctor or pharmacist if you are taking at present or have recently taken any other medicines with or without a prescription.*

### **3. How to take ROLINOZ**

#### **Posology/frequency of administration and period**

**Children aged from 2 to 6 years:** 2.5 mg (5 drops) is administered once a day. In this age group, the daily dose can be increased to 5 mg. It can be administered 5 mg (10 drops) once a day or 2.5 mg (5 drops) twice a day (every 12 hours).

**Children aged from 6 to 12 years:** Depending on the severity of the symptoms, 5 mg (10 drops) or 10 mg (20 drops) is administered once a day, or it can be administered by dividing the daily dose into two.

**Children aged 12 years above and Adults :** Depending on the severity of the symptoms, 5 mg (10 drops) or 10 mg (20 drops) are administered once a day.

#### **Administration route and method:**

ROLINOZ is for oral use.

#### **Different age groups:**

**Using in elderly:** No dose reduction is necessary if renal function is normal.

#### **Special usage conditions:**

##### **Renal/hepatic impairment:**

If you have renal impairment and hepatic impairment, 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 the doctor, taking into account renal function (function) and body weight.



Only patients with hepatic impairment can take the usual prescribed dose. Dose adjustment is recommended in patients with both renal and hepatic impairment.

*If you take impression about effect of ROLINOZ whether its affect stronger or weak, contact your doctor or pharmacist.*

**If you take more ROLINOZ than you should**

*If you take more ROLINOZ than you should, talk to your doctor or pharmacist immediately.*

**If you forget to take ROLINOZ**

Continue to take the medicine in accordance with the instructions given by your doctor.

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

**Effects that may occur when treatment with ROLINOZ is terminated**

The duration of treatment with ROLINOZ depends on the clinical manifestations and the individual course of the disease. Do not stop treatment without your doctor's advice, as this may cause the symptoms of the disease to reappear or get worse. Your doctor should decide to stop treatment with ROLINOZ.

**4. What are the possible side effects?**

Like all medicines, there may be side effects in people who are sensitive to the substances content of ROLINOZ.

**If any of the following occur, stop taking ROLINOZ and inform your doctor IMMEDIATELY or please refer to your nearest hospital emergency department:**

- Allergic reactions, including severe reactions and angioedema (a serious allergic reaction that causes swelling of the face or throat)

These reactions can begin right after or after taking the drug. The above-mentioned side effects are rare or very rare.



Side effects are listed as shown in the following categories:

**Very common:** It can be seen in at least 1 of 10 patients.

**Common** : It can be seen in less than 1 in 10 patients, but more than 1 in 100 patients.

**Uncommon** : It can be seen in less than 1 in 100 patients, but more than 1 in 1.000 patients.

**Rare** : It can be seen in less than 1 in 1.000 patients, but more than 1 in 1.0000 patients.

**Very rare** : It can be seen in less than 1 in 10.000 patients.

**Unknown** : It cannot be estimated from the available data.

**Common:**

- Somnolence (drowsiness)
- Feeling dizzy
- Headache
- Pharyngitis (pharyngitis)
- Rhinitis (cold)
- Diarrhea (diarrhea)
- Nausea
- Dry mouth
- Weakness
- Stomach ache

**Uncommon:**

- Agitation (extreme restlessness)
- Paresthesia (temporary absence of sensation, numbness/tingling)
- Itching
- Debris
- Asthenia (fatigue)
- Brokenness

**Rare:**

- Allergic reactions, some severe (very rare)
- Depression
- Hallucination (seeing/hearing things that are not real)
- Aggression (state of aggression)
- Confusion
- Insomnia
- Convulsions (involuntary muscle contractions, seizure, convulsions)
- Tachycardia (heart rate per minute - pulse - higher than normal)
- Liver function abnormality (increased transaminase, alkaline phosphatase, gamma-GT and bilirubin)
- Urticaria (hives)
- Edema
- Weight gain
- Hypersensitivity

**Very rare:**

- Thrombocytopenia [decreased number of platelets (cells that help blood clot) in the blood]
- Tic
- Syncope (fainting)
- Dyskinesia (difficulty moving voluntarily)
- Dystonia (involuntary twitches, spasms, or movements of the muscles)
- Tremble
- Taste disorder
- Blurred vision
- Accommodation disorder (eye adjustment disorder)
- Oculogyration (involuntary movement of the eyeball in any direction)
- Angioneurotic edema (swelling of the hands, feet, ankles, face, lips, or especially swelling of the mouth or throat that makes it difficult to swallow or breathe)
- Fixed drug eruption (rash)
- Enuresis (incontinence)



- Dysuria (painful urination)
- Anaphylactic shock (Immediate hypersensitivity response)

**Unknown:**

- Increased appetite
- Suicidal ideation
- Forgetfulness
- Memory impairment
- Dizziness due to balance disorder (vertigo)
- Inability to urinate, voiding difficulty

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

**5. How to store ROLINOZ**

*Keep ROLINOZ out of the reach and sight of children and in its package.*

Store at the room temperature below 30°C.

**Use in accordance with expiration dates.**

Do not use ROLINOZ after the expiry date on its package.

**Marketing Authorisation Holder:**

World Medicine İlaç San. ve Tic. A.Ş.  
Bağcılar/İstanbul/TURKEY

**Manufacturing site:**

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