



**PATIENT INFORMATION LEAFLET**

**ROLINOZ 10 mg Film-coated Tablets**

**It is taken orally.**

- **Active substance:** Cetirizine dihydrochloride  
Each film-coated tablet contains 10 mg cetirizine dihydrochloride.
- **Excipients:** Microcrystalline cellulose, Lactose monohydrate, Silica colloidal anhydrous, Sodium starch glycolate (Type A), Magnesium stearate, Polyvinyl alcohol, Titanium dioxide (E 171), Polyethylene glycol 3350 (Macrogol 400), Talc

**Read all of this LEAFLET carefully before you start using this medicine because 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.*

**In this leaflet:**

1. *What ROLINOZ and what it is used for?*
2. *Before you take ROLINOZ*
3. *How to take ROLINOZ?*
4. *Possible side effects*
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## **1. What ROLINOZ is and what it is used for?**

ROLINOZ 10 mg Film-coated Tablets is white, oblong, two sided-notched film-coated tablets. There are 10 tablets in cardboard boxes.

ROLINOZ 10 mg Film-coated Tablets is a drug used in the treatment of allergic rhinitis, perennial unknown rash and itching.

ROLINOZ 10 mg Film-coated Tablets;

In adults and children aged 6 years and above:

- Cetirizine is used in the treatment of the allergic rhinitis symptoms related with nose and eye, the symptoms of chronic idiopathic urticaria (perennial unknown rash) and itching.

## **2. Before You Take ROLINOZ**

**Do not take ROLINOZ in the following cases,**

- If you have hypersensitivity story to the active substance of ROLINOZ or to any of the excipients, to hydroxyzine or to any piperazine derivatives.
- If you have severe renal failure that your creatinine clearance is less than 10 mL/min (the cleaning of creatinine which is a substance used to monitor the kidney function, from blood by the kidneys).
- If you have been told by your doctor that you have intolerance against some sugars, contact with your doctor before you take this medicinal product.

### **TAKE SPECIAL CARE with ROLINOZ**

- If you take ROLINOZ with alcohol, be careful.
- If you have urination problems (spinal problems or prostate or bladder problems), consult your doctor.
- If you need to make an allergy test, ask your doctor whether stop treatment with ROLINOZ a few days before the test or not. ROLINOZ may affect the results of allergy test.

If any of these warnings applies 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 or full stomach.

### **Pregnancy**

*Ask your doctor or pharmacist before taking this medicine.*

Available clinical data on the use of ROLINOZ in pregnant women is very few. Although animal studies have not showed a detrimental effect, it is recommended to use ROLINOZ during pregnancy with care when it is absolutely necessary.

*If you notice that you are pregnant during treatment, consult your doctor immediately.*

### **Breast-feeding**

*Consult your doctor or pharmacist before taking medicine if you are breastfeeding your baby.*

Use of ROLINOZ is not recommended in breast-feeding women because the active substance (cetirizine) in ROLINOZ content passes into breast milk

### **Driving and using machines**

The recommended 10 mg dose ROLINOZ has not showed a significant effect clinically on the efficiency of driving ability, dozing off and simulated assembly line (measurement test of drug used in measurement of drug drowsiness / somnolence effect, representing the performance of the real business environment, performed with computer and sensitive to all somnolence variables.

Patients planning to drive, working in dangerous work potentially and using machine should not exceed the recommended dose and should take their response to the drug. In such sensitive patients, the concurrent use of ROLINOZ with alcohol or other central nervous system depressants (suppressors) may lead to a decrease in alertness and performance impairment.

**Important information about some of the ingredients in ROLINOZ**

Lactose is present in ROLINOZ 10 mg Film-coated tablets. If your doctor has indicated that you are sensitive to some types of sugars, consult your doctor before taking this medicine.

**Taking with other medicines**

There is no known significant interaction of ROLINOZ with other drugs clinically.

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

**3. HOW TO TAKE ROLINOZ ?**

**Instructions for proper use and dose/administration frequency:**

**Adults and children aged 6 years and over:** 5 mg (1/2 tablet) or 10 mg (1 tablet) is administered once a day depending on the severity of symptoms.

**Administration route and method:**

ROLINOZ Tablets is for oral administration.

Swallow ROLINOZ Tablets with sufficient amount of liquid (e.g. a glass of water).

**Various age groups:**

**Use in children:** Use of ROLINOZ 10 mg Film-coated Tablets in children under the age of 6 is not recommended because this formulation does not allow the correct dose adaptation.

**Use in elderly:** If kidney function is normal, no need to reduce the dose.

**Special use cases**

**Kidney/Liver failure:**

If you have kidney and liver failure, dose is adjusted by your doctor according to the severity of renal failure.

Dose in children with renal failure should be individually adjusted by the doctor by taking renal function and body weight into consideration.

Only patients with liver failure may receive the normal prescribed dose. Dose adjustment is recommended in patients with both renal and liver failure.

*If have an impression about that effect of ROLINOZ is too strong of too weak, consult 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 drug according to the instructions that your doctor has told you.

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

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

The duration of treatment with ROLINOZ depends on the clinical symptoms and individual disease progression.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, side effects may occur in the ones who are sensitive to the ingredients in ROLINOZ content.

**If you have any of the following, stop using ROLINOZ and inform your doctor IMMEDIATELY or contact the emergency department of your nearest hospital:**

Thrombocytopenia (decreased number of platelets (blood clotting cells))

Anaphylactic shock (Sudden hypersensitivity reaction)

Hypersensitivity

Confusion (mental confusion)

Hallucination (seeing/hearing unreal things)

Convulsions (involuntary muscle contractions, seizures, convulsion)

Syncope (fainting)

Shivering

Accommodation impairment (visual impairment)

Blurred vision

Oculogyrral on (involuntary movement of eye ball in any direction)

Tachycardia (The number of heartbeats per minute - the pulse is above normal)

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

Angioneurotic edema (oedema of hands, feet, ankles, face, lips or especially oedema of mouth and throat which makes swallowing or breathing difficult)

These are all serious side effects. If you have one of them, you are seriously allergic to ROLINOZ. You may be required an emergency medical intervention or hospitalization.

These serious side effects are seen very rare.

**If you notice any of these below, tell your doctor immediately.**

Weakness

Dizziness

Headache

Dry mouth

Nausea

Somnolance

Rhinitis

Pharyngitis

Diarrhoea

Aggression

Agitation

Dysmnnesia  
Memory disorder  
Insomnia  
Tic  
Taste disorder  
Dyskinesia (difficulty in voluntary act)  
Paresthesia (temporary absence of sensation, numbness / tingling)  
Itching  
Rash  
Urticaria  
Constant drug eruption (rash)  
Dysuria (painful urination)  
Enuresis (urinary incontinence)  
Asthenia (fatigue)  
Indisposition  
Weight gain  
Stomach ache  
Depression  
Oedema  
Dystonia (involuntary twitching, spasms and motions of muscles)  
Increased appetite  
Suicidal ideation  
Dizziness due to balance disorder (vertigo)  
Unable to void, difficulty in urination

These are slight side effects of ROLINOZ.

*Please inform your doctor or pharmacist if you experience any side effect that is not included in this patient information leaflet.*

### **5. HOW TO STORE ROLINOZ ?**

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

Store below 30°C at room temperature.

**Use in accordance with the expiry date.**

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

### **Marketing Authorization Holder:**

World Medicine İlaç San. ve Tic. A.Ş.

Bağcılar/İstanbul/TURKEY

### **Manufacturing Site:**

World Medicine İlaç San. ve Tic. A.Ş.

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