

**PATIENT INFORMATION LEAFLET**

**ESLOTIN 5 mg Film Coated Tablets**

Taken orally.

- **Active substance:** Each film coated tablet contains 5 mg Desloratadine.
- **Excipients:** It contains Dibasic calcium phosphate anhydrous, Maize starch, Microcrystalline cellulose, Talc, Magnesium stearate and Opadry blue 85F20400 [Polyvinyl alcohol, Macrogol, Titanium dioxide (E171), Talc, Indigo carmine aluminum lake (E132)].

**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 ESLOTIN is and what it is used for**

ESLOTIN 5 mg Film Coated Tablets is presented in packaging containing 10, 20 and 30 tablets.

ESLOTIN contains Desloratadine from a class of antihistamine drugs.

ESLOTIN is an antiallergy drug that does not cause drowsiness. It helps to control allergic reactions and allergy symptoms.

ESLOTIN relieves the symptoms associated with allergic cold such as sneezing, runny nose and itching, itching of the palate and itching of the eyes, redness or tearing (e.g. hay fever, allergy to house dust mite).

ESLOTIN is also used to relieve symptoms that occur with urticaria (a skin disorder caused by allergy), such as itching, swelling and redness of the skin.

These symptoms will be relieved all day long and help you regain your normal daily activities and sleep.

## **2. Before you take ESLOTIN**

### **DO NOT USE ESLOTIN on the following cases**

If,

- You are hypersensitive (allergic) to Desloratadine, loratadine or any of the excipients in this drug.

### **TAKE SPECIAL CARE with ESLOTIN on the following cases**

- If you have poor renal function, talk to your doctor or pharmacist before taking ESLOTIN.

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

### **Taking ESLOTIN with food and drink**

ESLOTIN can be taken on an empty or full stomach.

### **Pregnancy**

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

If you are pregnant, think you may be pregnant or are planning to have a baby, consult your doctor or pharmacist before taking this drug.

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

It is not recommended to use ESLOTIN if you are pregnant.

### **Breast feeding**

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

It is not recommended to use ESLOTIN if you are breastfeeding your baby.

### **Driving and using machines**

At recommended doses, this drug is not expected to affect your ability to drive or use machines. Although most patients do not experience somnolence, it is recommended that you do not engage in activities that require mental alertness, such as driving or using machines, until you understand your response to the medicinal product.

### **Important information about some of the ingredients of ESLOTIN**

There are no excipients in the content of ESLOTIN that will require any warning.

### **Use with other drugs**

ESLOTIN has no known interactions with other drugs.

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

### **3. How to take ESLOTIN**

Always take this drug exactly as your doctor or pharmacist has told you. If you are unsure, consult your doctor or pharmacist.

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

Adults and children 12 years and older: Take one tablet once a day. Take the tablet with water, with or without food.

This drug is used orally. Swallow the tablet whole with a glass of water, either on an empty stomach or on a full stomach.

Regarding the duration of treatment, your doctor will determine the type of allergic cold in you and decide how long you should take ESLOTIN.

If your allergic cold is intermittent (presence of symptoms for less than 4 days a week or for less than 4 weeks), your doctor will evaluate the history of the disease and recommend you a treatment program accordingly.

If your allergic cold is persistent (presence of symptoms for 4 days or more a week and for more than 4 weeks), your doctor may recommend you a longer course of treatment.

The treatment duration of urticaria may differ from patient to patient, so you should follow your doctor's instructions.

**Route and method of administration:**

This drug is used orally.

Swallow the tablet whole with a glass of water, either on an empty stomach or on a full stomach.

**Different age groups:**

**Use in children**

Do not give this drug to children younger than 12 years old.

**Use in elderly**

The efficacy and safety of Desloratadine in the elderly have not yet been established.

**Special usage conditions:**

**Hepatic impairment**

There are no data on its use in hepatic impairment.

**Renal impairment**

ESLOTIN should be used carefully in severe renal impairment.

*If you have an impression about that effect of ESLOTIN is too strong or too weak, consult your doctor or pharmacist.*

**If you take more ESLOTIN than you should**

Use ESLOTIN only as it has been prescribed for you. Serious problems associated with accidental overdose are not expected.

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

**If you forget to take ESLOTIN**

If you forget to take the dose you need to take on time, take that dose as soon as you remember, then continue your treatment as usual.

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

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

No effects have been reported.

**If you stop using ESLOTIN**

If you have any further questions on the use of this drug, ask your doctor or pharmacist.

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

Like all drugs, this medicine can cause side effects.

Undesirable events are classified according to the following frequencies:

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

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

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

Rare : It can be seen in less than one in 1.000 patients, but more than one in 10.000 patients.

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

Unknown : The frequency cannot be estimated from the available data.

**If you have any of the following symptoms, stop taking ESLOTIN and tell your doctor IMMEDIATELY or go to emergency department of the closest hospital:**

At the time Desloratadine was marketed, cases of severe allergic reactions (difficulty breathing, wheezing, itching, hives and swelling) have been reported very rarely.

These are all serious side effects. Emergency medical intervention may be required. Serious side effects are seen very rare.

In clinical studies in adults, side effects were seen to be almost the same as those observed with the placebo tablet. However, fatigue, dry mouth and headache were reported more frequently than with the placebo tablet.

The following side effects have been reported in clinical studies carried out with ESLOTIN:

**Common:**

- Fatigue,
- Dry mouth,
- Headache.

These are mild side effects of ESLOTIN.

During the time Desloratadine was on the market, the following side effects were reported:

**Very rare:**

- Severe allergic reactions,
- Rash,
- Restlessness with increased body movement,
- Acceleration of the heartbeat,
- Abnormality in hepatic function tests,
- Inflammation in the liver,
- Stomachache,
- Nausea (feeling sick),

- Vomiting,
- Diarrhea,
- Insomnia,
- Somnolence,
- Muscle pain,
- Stomach discomfort,
- Hallucinations,
- Seizures.

**Unknown:**

- Increased sensitivity of the skin to the sun (even when it is cloudy) and UV rays (e.g. UV rays in tanning bed),
- Change in heartbeat rhythm,
- Yellowing of the skin and/or eyes,
- Unusual fatigue.

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

**5. How to store ESLOTIN**

Store at room temperature below 30°C by protecting from moisture.

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

**Use in accordance with expiry date.**

*Do not use ESLOTIN after the expiry date on the package or cardboard.*

If you notice any change in the appearance of the tablets, do not use them and inform your pharmacist.

**Marketing Authorisation Holder:**

World Medicine İlaç San ve Tic A.Ş.

Bağcılar, İstanbul / TURKEY

**Manufacturing Site:**

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