

## LEUKOTRIS® Tablets

**Dear patient,**

**Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.**

### **Information about LEUKOTRIS**

LEUKOTRIS is available as 10 mg, 5 mg and 4 mg tablets containing respectively montelukast sodium equivalent to 10 mg, 5 mg and 4 mg montelukast.

Other ingredients are: lactose monohydrate, microcrystalline cellulose, magnesium stearate, strawberry flavor, red erythrosine.

LEUKOTRIS tablets are for oral administration.

Montelukast is a leukotriene receptor antagonist. It binds to the CysLT<sub>1</sub> receptor and inhibits the physiologic actions of leukotrienes which are inflammatory mediators heavily implicated in asthma and allergic rhinitis pathophysiology.

LEUKOTRIS inhibits bronchoconstriction in asthmatics. It suppresses both early and late bronchoconstrictor responses to inhaled antigens or irritants.

LEUKOTRIS relieves the symptoms of allergic rhinitis such as nasal symptoms (sneezing, nasal congestion, runny nose, itching of the nose) and improves rhinoconjunctivitis.

LEUKOTRIS is indicated for use in adults and pediatric patients in the following cases:

- Prophylaxis of asthma
- Chronic treatment of asthma
- Prevention of exercise induced bronchoconstriction
- Relief of symptoms of seasonal and perennial allergic rhinitis

LEUKOTRIS is effective alone or in combination with other agents used in the maintenance treatment of chronic asthma or in allergic rhinitis.

### **The way to take LEUKOTRIS**

Take LEUKOTRIS as directed by your physician. Do not discontinue the treatment without consulting your doctor.

LEUKOTRIS should be taken once daily without regard to meals.

For asthma, it is recommended to take the dose in the evening.

For allergic rhinitis, the time of administration may be individualized to suit patients needs.

For patients with both asthma and allergic rhinitis, the dose is taken once daily in the evening.

For prevention of exercise induced bronchoconstriction, a single dose of LEUKOTRIS should be taken at least 2 hours before exercise.

The usual recommended doses for the management of asthma or allergic rhinitis are:

Adults and adolescents 15 years of age and older: 10 mg once daily

Pediatric patients 6-14 years of age: 5 mg once daily

Pediatric patients from 6 months to 5 years of age: 4 mg once daily

LEUKOTRIS can be administered either directly in the mouth or dissolved in a teaspoon containing some water and then administered. LEUKOTRIS dissolved tablet has a palatable taste, suitable for administration in pediatric patients.

### **In case of overdose**

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

### **In case of missed dose**

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

### **Contraindications**

This drug is contraindicated in case of known hypersensitivity to any of the components.

**Precautions**

- Do not take this medication for the immediate relief of an asthma attack. Other appropriate rescue medications must be available at your disposition to treat asthma exacerbations.
- If you have exacerbations of asthma after exercise you should continue to use your usual regimen of inhaled beta-agonists as prophylaxis unless otherwise instructed by your doctor.
- Take the medication daily as prescribed, even when you are asymptomatic, as well as during periods of worsening asthma. Contact your physician if your asthma is not well controlled.
- Do not decrease the dose or do not stop taking any other asthma medications unless instructed by your doctor.
- In case of known aspirin sensitivity you should continue avoidance of aspirin or non-steroidal anti-inflammatory agents while taking this medication.
- Consult your doctor before using this medication in case of pregnancy or lactation. This drug should be used during pregnancy only if clearly needed. It should be used with caution in nursing mothers.

**Associations with other medications**

Please inform your doctor if other medicines are being taken or have been taken recently.

LEUKOTRIS may be safely administered with commonly used treatments for asthma.

This drug must be used with caution with phenobarbital, phenytoin, and rifampicin.

**Adverse reactions**

LEUKOTRIS is generally well tolerated. The most reported adverse effects were headache, abdominal pain, diarrhea, cough, fatigue, fever, dyspepsia, nausea, dental pain, infectious gastroenteritis, dizziness, influenza, upper respiratory infection, sleep disorders and rash. Hypersensitivity reactions, elevations in liver enzyme values and systemic eosinophilia have been rarely reported.

Rarely, asthmatic patients taking asthma medications including this drug have experienced a condition that includes certain symptoms that do not go away or get worse.

Although a causal association between montelukast and these underlying conditions has not been established, you must inform your doctor if you experience any of the following symptoms, particularly if they are persistent and worsening: a feeling of pins and needles or numbness of arms or legs, flu-like illness, increasing breathlessness, severe sinusitis or rash.

Inform your doctor if any side effect appears or becomes bothersome.

**Storage**

Store at controlled room temperature (up to 30°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

**Pack Presentation**

LEUKOTRIS 10, montelukast sodium equivalent to 10 mg montelukast, pack of 30 tablets

LEUKOTRIS 5, montelukast sodium equivalent to 5 mg montelukast, pack of 30 tablets

LEUKOTRIS 4, montelukast sodium equivalent to 4 mg montelukast, pack of 30 tablets

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