



# RELIEFAST<sup>®</sup>

## Montelukast 10 mg

### Film-coated tablets

**Read this entire leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Reliefast 10 mg, film-coated tablets is and what it is used for
2. Before you take Reliefast 10 mg, film-coated tablets
3. How to take Reliefast 10 mg, film-coated tablets
4. Possible side effects
5. How to store Reliefast 10 mg, film-coated tablets
6. Further information

## 1. What Reliefast 10 mg, film-coated tablets is and what it is used for

**Reliefast** is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs and also cause allergic symptoms. By blocking leukotrienes, **Reliefast** improves asthma symptoms, helps control asthma and improves seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis). Your doctor has prescribed **Reliefast** to treat asthma, preventing your asthma symptoms during the day and night.

- **Reliefast** is used for the treatment of patients who are not adequately controlled on their medication and need additional therapy.
  - **Reliefast** also helps prevent the narrowing of airways triggered by exercise.
  - In those asthmatic patients in whom **Reliefast** is indicated in asthma, **Reliefast** can also provide symptomatic relief of seasonal allergic rhinitis.
- Your doctor will determine how **Reliefast** should be used depending on the symptoms and severity of your asthma.

### What is asthma?

Asthma is a long-term disease.

Asthma includes:

- difficulty breathing because of narrowed airways. This narrowing of airways worsens and improves in response to various conditions.
- sensitive airways that react to many things, such as cigarette smoke, pollen, cold air, or exercise.
- swelling (inflammation) in the lining of the airways.

Symptoms of asthma include: Coughing, wheezing, and chest tightness.

### What are seasonal allergies?

Seasonal allergies (also known as hay fever or seasonal allergic rhinitis) are an allergic response often caused by airborne pollens from trees, grasses and weeds. The symptoms of seasonal allergies typically may include: stuffy, runny, itchy nose; sneezing; watery, swollen, red, itchy eyes.

## 2. Before you take Reliefast 10 mg, film-coated tablets

Tell your doctor about any medical problems or allergies you have now or have had.

### Do not take Reliefast if you

- are allergic (hypersensitive) to montelukast or any of the other ingredients of **Reliefast** (see 6. Further information).

### Take special care with Reliefast

- If your asthma or breathing gets worse, tell your doctor immediately.
- Oral **Reliefast** is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you. Always have your inhaled rescue medicine for asthma attacks with you.
- It is important that you take all asthma medications prescribed by your doctor. **Reliefast** should not be substituted for other asthma medications your doctor has prescribed for you.
- Any patient on anti-asthma medicines should be aware that if he develops a combination of symptoms such as a flu-like illness, pins and needles or numbness of arms or legs, worsening of pulmonary symptoms, and/or rash, he should consult his doctor.
- You should not take acetyl-salicylic acid (aspirin) or anti-inflammatory medicines (also known as non-steroidal anti-inflammatory drugs or NSAIDs) if they make your asthma worse.

### Use in children

For children 2 to 5 years old, **Reliefast** 4 mg chewable tablets are available.

For children 6 to 14 years old, **Reliefast** 5 mg chewable tablets are available.

### Taking other medicines

Some medicines may affect how **Reliefast** works, or **Reliefast** may affect how other medicines work. Please tell your doctor or pharmacist if you are taking or have recently taken other medicines, including those obtained without a prescription.

Tell your doctor if you are taking the following medicines before starting **Reliefast**:

- phenobarbital (used for treatment of epilepsy),
- phenytoin (used for treatment of epilepsy),
- rifampicin (used to treat tuberculosis and some other infections).

### Food and drink

**Reliefast** 10 mg, film-coated tablets may be taken with or without food.

### Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine

**Use in pregnancy:** Women who are pregnant or intend to become pregnant should consult their doctor before taking **Reliefast**. Your doctor will assess whether you can take **Reliefast** during this time.

**Use in breast-feeding:** It is not known if **Reliefast** appears in breast milk. You should consult your doctor before taking **Reliefast** if you are breast-feeding or intend to breast-feed.

### Driving and using machines

**Reliefast** is not expected to affect your ability to drive a car or operate machinery. However, individual responses to medication may vary. Certain side effects (such as dizziness and drowsiness) that have been reported very rarely with montelukast may affect some patients' ability to drive or operate machinery.

### Important information about some of the ingredients of Reliefast 10 mg

**Reliefast** 10 mg, film-coated tablets contain lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## 3. How to take Reliefast 10 mg, film-coated tablets

- You should take only one tablet of **Reliefast** once a day as prescribed by your doctor.
- It should be taken even when you have no symptoms or have an acute asthma attack.
- Always take **Reliefast** as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- To be taken by mouth.

### For adults 15 years of age and older

One 10 mg tablet to be taken daily in the evening. **Reliefast** 10 mg may be taken with or without food. If you are taking **Reliefast**, be sure that you do not take any other products that contain the same active ingredient, montelukast.

### If you take more Reliefast than you should

Contact your doctor immediately for advice.

There were no side effects reported in the majority of overdose reports. The most frequently occurring symptoms reported with overdose in adults and children included abdominal pain, sleepiness, thirst, headache, vomiting, and hyperactivity.

### If you forget to take Reliefast

Try to take **Reliefast** as prescribed. However, if you miss a dose, just resume the usual schedule of one tablet once daily.

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

### If you stop taking Reliefast

**Reliefast** can treat your asthma only if you continue to take it.

It is important to continue taking **Reliefast** for as long as your doctor prescribes. It will help control your asthma.

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

## 4. Possible side effects

Like all medicines, **Reliefast** 10 mg film-coated tablets can cause side effects, although not everybody gets them. In clinical studies with montelukast, 10 mg film-coated tablets, the most commonly reported side effects (occurring in at least 1 of 100 patients and less than 1 of 10 patients treated) thought to be related to montelukast were:

- abdominal pain
- headache

These were usually mild and occurred at a greater frequency in patients treated with montelukast tablets than placebo (a pill containing no medication).

Additionally, the following side effects have been reported:

- increased bleeding tendency,
- allergic reactions including rash, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing,
- behaviour and mood related changes: dream abnormalities, including nightmares, hallucinations, irritability, feeling anxious, restlessness, agitation including aggressive behaviour, tremor, depression, trouble sleeping, suicidal thoughts and actions (in very rare cases),
- dizziness, drowsiness, pins and needles/numbness, seizure,
- palpitations,
- nosebleed,
- diarrhoea, dry mouth, indigestion, nausea, vomiting,
- hepatitis,
- bruising, itching, hives, tender red lumps under the skin most commonly on your shins (erythema nodosum),
- joint or muscle pain, muscle cramps,
- tiredness, feeling unwell, swelling, fever.

In asthmatic patients treated with montelukast, very rare cases of a combination of symptoms such as flu-like illness, pins and needles or numbness of arms and legs, worsening of pulmonary symptoms and/or rash (Churg-Strauss syndrome) have been reported. You must tell your doctor right away if you get one or more of these symptoms.

Ask your doctor or pharmacist for more information about side effects. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## 5. How to store Reliefast 10 mg, film-coated tablets

- Keep out of the reach and sight of children.
- Do not use **Reliefast** after the expiry date which is stated on the blister or outer package.
- Store below 25°C. Store in the original package in order to protect from light and moisture.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. Further information

### What Reliefast 10 mg, film-coated tablets contains

*Active substance:* montelukast (as montelukast sodium).

One film-coated tablet contains montelukast sodium, which is equivalent to 10 mg of montelukast.

*Excipients:* Tablet core: lactose monohydrate (133,60 mg), microcrystalline cellulose, croscarmellose sodium, hydroxypropyl cellulose (E463), magnesium stearate.

Film coating: hydroxypropyl cellulose (E463), hypromellose, titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172), iron oxide black (E172).

### What Reliefast 10 mg, film-coated tablets looks like and contents of the pack

**Reliefast** 10mg, film-coated tablets are beige, biconvex, round, debossed "10" on one side.

**Reliefast** 10mg, film-coated tablets, is available in packs of 28 tablets.

**Manufactured by:** Pabianickie Zakłady Farmaceutyczne Polfa S.A.

Pabianice, Poland

**For:** ARWAN Pharmaceutical Industries Lebanon s.a.l.

Jadra, Lebanon

### THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.

**Council of Arab Health Ministers, Union of Arab Pharmacists**