

Patient Information Leaflet (PIL)

Airfast® 4 mg Chewable Tablets

For children from 2 to 5 years of age

Airfast® 5 mg Chewable Tablets

For children from 6 to 14 years of age

Montelukast

Read all of this 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 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:

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1. What **Airfast** is and what it is used for

Airfast is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs.

By blocking leukotrienes, **Airfast improves asthma symptoms and helps to control asthma.**

Your doctor has prescribed this medicine to treat asthma, preventing asthma symptoms during the day and night.

- This medicine is used for the treatment of patients who are not adequately controlled on their medication and need **additional therapy.**

- This medicine may also be used as an **alternative treatment to inhaled corticosteroids** for patients who have not recently taken oral corticosteroids for their asthma and have shown that they are unable to use inhaled corticosteroids.

- This medicine also helps **prevent the narrowing of airways** triggered by exercise.

Your doctor will determine how this medicine should be used depending on the symptoms and severity of you and your child's asthma.

What is asthma?

Asthma is a long-term disease.

Asthma includes:

- Difficulty breathing because 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.

2. Before you take **Airfast**

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

Do not take **Airfast** if you or your child

- Is allergic (hypersensitive) to montelukast or any of the other ingredients in this medicine.

Take special care with **Airfast**

- If you or your child's asthma or breathing gets worse, tell your doctor immediately.

- **These oral tablets are not meant to treat acute asthma attacks.** If an asthma attack occurs, follow the instructions your doctor has given you or your child. Always have your or your child's inhaled rescue medicine for asthma attacks with you.

- It is important that you or your child takes all asthma medicines prescribed by the doctor. **These tablets should not be used instead of other asthma medications the doctor has prescribed for you or your child.**

- Any patient on anti-asthma medicines, should be aware that if he/she develops a combination of different symptoms such as flu-like illness, pins and needles or numbness of arms or legs, worsening of pulmonary symptoms, and/or rash occur, you should consult your doctor.

- You or your child should not take **aspirin** (acetyl-salicylic acid) or **other anti-inflammatory medicines** (also known as non-steroidal anti-inflammatory drugs or NSAIDs) if they make your asthma worse.

Taking other medicines

Some medicines may affect how your tablets work, or these tablets may affect how other medicines work.

Please tell your doctor or pharmacist if you or your child is taking or has recently taken other medicines, including those obtained without a prescription.

Tell the doctor if you or your child is taking one of the following medicines before starting this medicine:

- Phenobarbital (used for treatment of epilepsy).

- Phenytoin (used for treatment of epilepsy).

- Rifampicin (used to treat tuberculosis and some other infections).

Taking **Airfast** with food and drink

These tablets should not be taken immediately with food; they should be taken at least 1 hour before or 2 hours after food.

Pregnancy and breast-feeding

Use in pregnancy:

Women who are pregnant or intend to become pregnant should consult their doctor before taking this medicine. Your doctor will assess whether you can take this medicine during this time.

Use in breast-feeding:

It is not known if montelukast appears in breast milk. You should consult your doctor before taking this medicine if you are breast-feeding or intend to breast-feed.

Driving and using machines

This subsection is not applicable for the montelukast 4 mg chewable tablets since they are intended for use in children 2 to 5 years of age, however the following information is relevant to the active ingredient, montelukast.

This medicine is not expected to affect your ability to drive 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 these tablets may affect some patients' ability to drive or operate machinery.

Important information about some of the ingredients of **Airfast**

These tablets contain aspartame, a source of phenylalanine. May be harmful for children with phenylketonuria. If your child has phenylketonuria (a rare, hereditary disorder of the metabolism) you should take into account that **Airfast** 4 mg and 5 mg chewable tablets contain phenylalanine (a component of aspartame), 4.04 and 5.05 mg per 4 mg and 5 mg chewable tablet, respectively.

3. How to take **Airfast**

- You or your child should take only one tablet of this medicine once a day as prescribed by your doctor.

- It should be taken even when you or your child has no symptoms or has an acute asthma attack.

- Always take the tablets 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 children 2 to 5 years of age:

One 4 mg chewable tablet daily to be taken in the evening. The tablet should not be taken immediately with food; it should be taken at least 1 hour before or 2 hours after food.

For children 6 to 14 years of age:

One 5 mg chewable tablet daily to be taken in the evening. The tablet should not be taken immediately with food; it should be taken at least 1 hour before or 2 hours after food.

If you or your child is taking this medicine, be sure that you or your child does not take any other medicines that contain the same active ingredient, montelukast.

If you or your child takes more **Airfast** 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 **Airfast** or give **Airfast** to your child

Try to take this medicine as prescribed. However, if you or your child misses 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 or your child stops taking **Airfast**

This medicine can treat you or your child's asthma only if you or your child continues taking it. It is important to continue taking the tablets for as long as your doctor prescribes. It will help control you or your child's asthma.

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

4. Possible side effects

Like all medicines this medicine can cause side effects, although not everybody gets them.

Seek immediate medical advice if you or your child experiences allergic reactions including rash, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing.

Tell your doctor right away if you or your child experiences any behaviour and mood related changes such as:

Dream abnormalities, including nightmares, hallucinations, irritability, feeling anxious, restlessness, agitation including aggressive behaviour or hostility, tremor, depression, trouble sleeping, sleepwalking, suicidal thoughts and actions (in very rare cases).

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 or your child gets one or more of these symptoms.

In clinical studies with these tablets, the most commonly reported side effects (occurring in at least 1 of 100 patients and less than 1 of 10 paediatric patients treated) thought to be related to the medicine were:

- Abdominal pain.

- Thirst.

Additionally, the following side effect was reported commonly in clinical studies with the 10 mg film coated tablets and the 5 mg chewable tablets:

- Headache.

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

Additionally, while the medicine has been on the market, the following have been reported:

- Upper respiratory infection.

- Increased bleeding tendency.

- Dizziness, drowsiness, pins and needles/numbness, seizure.

- Palpitations.

- Nosebleed.

- Diarrhea, dry mouth, indigestion, nausea, vomiting.

- Hepatitis (inflammation of the liver).

- 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.

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, please tell your doctor or pharmacist.

5. How to store **Airfast**

Store below 30°C.

Do not use beyond the expiry date or if the product shows any sign of deterioration.

6. Further information

What **Airfast** contains:

Airfast 4 mg: Each chewable tablet contains: Montelukast sodium equivalent to montelukast 4 mg.

Airfast 5 mg: Each chewable tablet contains: Montelukast sodium equivalent to montelukast 5 mg.

Excipients: Sorbitol, cellulose, sodium starch glycolate, colloidal silicon dioxide, magnesium stearate, aspartame, ferric oxide red and cherry flavor.

Presentations:

Packs of 30 Chewable Tablets.

Hospital packs are available.

To report any side effect(s):

• Saudi Arabia:

National Pharmacovigilance Center (NPC)

Fax: +966-11-205-7662

E-mail: npc.drug@sfd.gov.sa

Website: www.sfd.gov.sa/npc

• Other GCC States:

Please contact the relevant competent authority.

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THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
 - Strictly follow 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 medicine, its 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 medicament out of reach of children.**

Council of Arab Health Ministers & Union of Arab Pharmacists.



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