

Patient Information Leaflet (PIL)

Airfast® Pediatrics 4 mg Granules
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 your child. Do not pass it on to others. It may harm them, even if their symptoms are the same as your child's.
- 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 **Airfast pediatrics** is and what it is used for
2. Before **Airfast pediatrics** is taken
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1. What **Airfast pediatrics** is and what it is used for

Airfast pediatrics is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in your lungs. By blocking leukotrienes, **Airfast pediatrics** improves asthma symptoms and helps control asthma.

Your doctor has prescribed **Airfast pediatrics** to treat your child's asthma, preventing asthma symptoms during the day and night.

- **Airfast pediatrics** is used for the treatment of 6 months to 5 year old patients who are not adequately controlled on their medication and need additional therapy.

- **Airfast pediatrics** may also be used as an alternative treatment to inhaled corticosteroids for 2 to 5 year old patients who have not recently taken oral corticosteroids for their asthma and have shown that they are unable to use inhaled corticosteroids.

- **Airfast pediatrics** also helps prevent the narrowing of airways triggered by exercise for patients 2 years of age and older.

Your doctor will determine how **Airfast pediatrics** should be used depending on the symptoms and severity of your child's 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.

2. Before **Airfast pediatrics** is taken

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

Do not give **Airfast pediatrics** to your child if he/she

- Is allergic (hypersensitive) to montelukast or any of the other ingredients of **Airfast pediatrics**.

Warnings and precautions

Take special care with **Airfast pediatrics**:

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

- Oral **Airfast pediatrics** is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you for your child. Always have your child's inhaled rescue medicine for asthma attacks with you.

- It is important that your child take all asthma medications prescribed by your doctor. **Airfast pediatrics** should not be used instead of other asthma medications your doctor has prescribed for your child.

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

- Your child should not take acetyl-salicylic acid (aspirin) or anti-inflammatory medicines (also known as non-steroidal anti-inflammatory drugs or NSAIDs) if they make his/her asthma worse.

- Serious neuropsychiatric events that may include suicidal thoughts or actions have been reported in patients taking montelukast.

- Ask patients about any history of psychiatric illness prior to initiating treatment.

- Consider the risks and benefits of montelukast when deciding to prescribe or continue patients on the medicine.

- Monitor all patients treated with montelukast for neuropsychiatric symptoms. Events have occurred in patients with and without pre-existing psychotic disease.

- Advise patients and parents/caregivers that the patient should stop taking montelukast and contact a health care professional immediately if changes in behavior or new neuropsychiatric symptoms, suicidal thoughts or behavior occur.

- Most reported cases of neuropsychiatric events occurred during montelukast treatment, but same occurred after discontinuation.

Patients should be aware that various neuropsychiatric events (for example behaviour and mood-related changes) have been reported in adults, adolescents and children with Montilukast. If you or your child develop(s) such symptoms while taking montilukast, you should consult your or child's doctor.

Taking other medicines:

Some medicines may affect how **Airfast pediatrics** works, or **Airfast pediatrics** may affect how your child's other medicines work.

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

Tell your doctor if your child is taking the following medicines before starting **Airfast pediatrics**:

- Phenobarbital (used for treatment of epilepsy).
- Phenytoin (used for treatment of epilepsy).
- Rifampicin (used to treat tuberculosis and some other infections).

Taking **Airfast pediatrics** with food and drink:

Airfast pediatrics granules can be taken without regard to the timing of food intake.

Pregnancy and breast-feeding:

This subsection is not applicable for the **Airfast pediatrics** 4 mg granules since they are intended for use in children 6 months to 5 years of age, however the following information is relevant to the active ingredient, montelukast.

Use in pregnancy:

Women who are pregnant or intend to become pregnant should consult their doctor before taking **Airfast**.

Your doctor will assess whether you can take **Airfast** during this time.

Use in breast-feeding:

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

Driving and using machines:

This subsection is not applicable for the **Airfast pediatrics** 4 mg granules since they are intended for use in children 6 months to 5 years of age, however the following information is relevant to the active ingredient, montelukast.

Airfast 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 **Airfast** may affect some patients' ability to drive or operate machinery.

Airfast pediatrics contains Mannitol

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take **Airfast pediatrics**

This medicine is to be given to a child under adult supervision. Your child should take **Airfast pediatrics** every evening.

- It should be taken even when your child has no symptoms or if he/she has an acute asthma attack.

- Always have your child take **Airfast pediatrics** as your doctor has told you. You should check with your child's doctor or pharmacist if you are not sure.

- To be taken by mouth.

For children 6 months to 5 years of age:

One sachet of **Airfast pediatrics** 4 mg granules to be taken by mouth each evening.

If your child is taking **Airfast pediatrics**, be sure that your child does not take any other products that contain the same active ingredient, montelukast.

For children 6 months to 2 years old, **Airfast pediatrics** 4 mg granules are available.

For children 2 to 5 years old, **Airfast** 4 mg chewable tablets and

Airfast pediatrics 4 mg granules are available. The **Airfast pediatrics** 4 mg granules formulation is not recommended below 6 months of age.

How should I give **Airfast pediatrics** granules to my child?

- Do not open the sachet until ready to use.
- **Airfast pediatrics** granules can be given either:
 - Directly in the mouth.
 - Or mixed with a spoonful of cold or room temperature soft food (for example, Applesauce, ice cream, carrots and rice).
- Mix all of the contents of the **Airfast pediatrics** granules into a spoonful of cold or room temperature soft food, taking care to see that the entire dose is mixed with the food.
- Be sure the child is given the entire spoonful of the granule/food mixture immediately (within 15 minutes).
IMPORTANT: Never store any granule/food mixture for use at a later time.
- **Airfast pediatrics** granules are not intended to be dissolved in liquid. However, your child may take liquids after swallowing the **Airfast pediatrics** granules.
- **Airfast pediatrics** granules can be taken without regard to the timing of food intake.

If your child takes more **Airfast pediatrics** than he/she should:

Contact your child's 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 give **Airfast pediatrics** to your child

Try to give **Airfast pediatrics** as prescribed. However, if your child misses a dose, just resume the usual schedule of one sachet once daily.

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

If your child stops taking **Airfast pediatrics**

Airfast pediatrics can treat your child's asthma only if he/she continues taking it.

It is important for your child to continue taking **Airfast pediatrics** for as long as your doctor prescribes. It will help control 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, **Airfast pediatrics** can cause side effects, although not everybody gets them.

In clinical studies with montelukast 4 mg granules, the most commonly reported side effects (occurring in at least 1 of 100 patients and less than 1 of 10 pediatric patients treated) thought to be related to montelukast were:

- Diarrhea.
- Hyperactivity.
- Asthma.
- Scaly and itchy skin.
- Rash.

Additionally, the following side effects were reported in clinical studies with either montelukast 10 mg film coated tablets, montelukast 5 mg or 4 mg chewable tablets:

- Abdominal pain.
- Headache.
- Thirst.

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

The frequency of possible side effects listed below is defined using the following convention:

Very common (affects at least 1 user in 10)

Common (affects 1 to 10 users in 100)

Uncommon (affects 1 to 10 users in 1,000)

Rare (affects 1 to 10 users in 10,000)

Very rare (affects less than 1 user in 10,000)

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

- Upper respiratory infection (Very common).
- Increased bleeding tendency (Rare).
- Allergic reactions including rash, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing (Uncommon).
- Behaviour and mood related changes (dream abnormalities, including nightmares, trouble sleeping, sleep walking, irritability, feeling anxious, restlessness, agitation including aggressive behaviour or hostility, depression (Uncommon); tremor (Rare); hallucinations, suicidal thoughts and actions (Very rare)).
- Dizziness, drowsiness, pins and needles/numbness, seizure (Uncommon).
- Palpitations (Rare).
- Nosebleed (Uncommon).
- Diarrhea, nausea, vomiting (Common); dry mouth, indigestion (Uncommon).
- Hepatitis (inflammation of the liver) (Very Rare).
- Bruising, itching, hives (Uncommon), tender red lumps under the skin most commonly on your shins (erythema nodosum) (Very Rare).
- Joint or muscle pain, muscle cramps (Uncommon).
- Fever (Common); tiredness, feeling unwell, swelling (Uncommon).
- Stuttering (Dysphemia) and obsessive-compulsive symptoms which are potential neuropsychiatric adverse events. (very rare).

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 your child gets 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 child's doctor or pharmacist.

5. How to store **Airfast pediatrics**

Keep out of reach of children.

Store below 30°C.

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away the medicines you no longer use. These measures will help to protect the environment.

6. Further information

What **Airfast pediatrics** sachet contains:

Each sachet contains: Montelukast Sodium equivalent to Montelukast 4 mg.

Excipients: Mannitol, povidone, and sodium stearyl fumarate.

Presentations:

Packs of 28 Sachets.

Hospital packs are available.

® is a trademark.

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.



Manufactured by:

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