

# AIRLUKAST TABLETS

Montelukast Sodium Tablets( 10 mg)

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All medicines have risks and benefits. Your doctor has weighed the risks of you taking **AIRLUKAST TABLETS** against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

## What **AIRLUKAST TABLETS** is used for

**AIRLUKAST TABLETS** is used for

- prevention and treatment of asthma in adults
- relief of day time and night time symptoms of seasonal allergic rhinitis in adults.

Symptoms of asthma include coughing, wheezing and chest tightness. Not all people with asthma wheeze. For some, coughing may be the only symptom of asthma. Symptoms often occur during the night or after exercise.

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

## How **AIRLUKAST TABLETS** works

**AIRLUKAST TABLETS** contain the active ingredient, montelukast which is a

leukotriene receptor antagonist that blocks substances called leukotrienes.

Leukotrienes cause narrowing and swelling of airways in your lungs. By blocking leukotrienes, montelukast improves asthma symptoms, helps control asthma and improves seasonal allergic rhinitis symptoms.

**Ask your doctor if you have any questions about why **AIRLUKAST TABLETS** has been prescribed for you.** Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

**AIRLUKAST TABLETS** are available as 10 mg tablets for adults

## Before you use **AIRLUKAST TABLETS**

- *When you must not take it*

Do not take **AIRLUKAST TABLETS** if you have an allergy to:

- any medicine containing montelukast
- any of the ingredients of **AIRLUKAST TABLETS**, listed at the end of this leaflet
- Some of the symptoms of an allergic reaction may include: shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Montelukast have not been studied in pregnant women.

It may affect your developing baby if you take it during pregnancy.

Your doctor will decide whether to give you this medicine or not.

It is not known if montelukast passes into breast milk.

Caution is required, if you are taking this medicine during breast-feeding.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

The expiry date refers to the last day of that month.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine talk to your doctor.

- *Before you start to take it*

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- **AIRLUKAST TABLETS** are not meant to treat acute asthma attacks including status asthmaticus. If an attack occurs, follow the instructions of your doctor. Always have your inhaled rescue medicine for asthma attacks with you.
- It is important that you take all asthma medications prescribed by your doctor. **AIRLUKAST TABLETS** should not be substituted for other asthma medications your doctor has prescribed for you.
- 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.
- If you develop behaviour and mood-related changes such as agitation; aggressive behaviour or hostility; feeling anxious; depression; dream abnormalities; seeing, feeling or hearing things that are not there (also called hallucinations); difficulty sleeping; irritability; restlessness; sleep walking; suicidal thinking and behaviour (including suicide) and tremor.

Talk to your doctor as soon as possible.

- If you develop frequent infections such as fever, severe chills, sore throat or mouth
- ulcers (may be due to low white blood cells), inflammation of blood vessels, often with skin rash consistent with a syndrome called Churg-Strauss syndrome (a condition which will be treated by your doctor with steroids), pins and needles or numbness of arms

or legs, worsening of lung symptoms and heart problems.

- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **AIRLUKAST Tablets 10 mg**

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

If you have not told your doctor about any of the above, tell them before you start taking **AIRLUKAST TABLETS**.

**- Taking other medicines**

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and **AIRLUKAST TABLETS** may interfere with each other. These include:

- phenobarbital, phenytoin; medicines used to treat epilepsy/ fits
- rifampicin, a medicine used to treat tuberculosis and some other infections

These medicines may be affected by **AIRLUKAST TABLETS**, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking **AIRLUKAST TABLETS**.

**How to take AIRLUKAST TABLETS**

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

**- How much to take**

Your doctor or pharmacist will tell you how much and how often you should take **AIRLUKAST TABLETS**.

For adults and adolescents 15 years and older, the recommended dose is one 10 mg tablet once in a day.

**- How to take it**

Swallow the 10 mg tablet with a glass of water.

**- When to take it**

**Asthma:**

Take **AIRLUKAST TABLETS** at bedtime each day.

Take your medicine at about bedtime each day.

Taking it at bedtime each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

**Seasonal allergic rhinitis:**

**AIRLUKAST TABLETS** are usually taken once a day.

Your doctor will advise you on the best time of the day to take your tablet.

**Asthma and seasonal allergic rhinitis:**

Take your **AIRLUKAST TABLETS** at bedtime each day if you have both asthma and seasonal allergic rhinitis.

It does not matter if you take **AIRLUKAST TABLETS** before or after food.

**- How long to take it**

Continue taking **AIRLUKAST TABLETS** for as long as your doctor tells you.

**AIRLUKAST TABLETS** helps control your asthma and/or seasonal allergic rhinitis. Therefore **AIRLUKAST TABLETS** must be taken every day.

**- If you forget to take it**

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your tablets as you do normally.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

**- If you take too much (overdose)**

Immediately telephone your doctor for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much **AIRLUKAST TABLETS**. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

**While you are taking AIRLUKAST TABLETS**

**- Things you must do**

Continue taking **AIRLUKAST TABLETS** every day as directed by your doctor, even if you have no asthma symptoms or if you have an asthma attack.

If your asthma gets worse while taking **AIRLUKAST TABLETS**, tell your doctor immediately.

If an acute attack of asthma occurs, follow your doctor's instructions on what reliever medicine to use to relieve the attack.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking **AIRLUKAST TABLETS**.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

**- Things you must not do**

Do not take **AIRLUKAST TABLETS** to relieve an acute asthma attack. In case of an acute asthma attack, follow your doctor's instructions on what reliever medicine to use.

Do not take **AIRLUKAST TABLETS** to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine because you are feeling better, unless advised by your doctor.

**Side Effects**

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking **AIRLUKAST TABLETS**.

This medicine helps most people with asthma and/or seasonal allergic rhinitis, but it may have unwanted side effects in a

few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they **worry you:**

- fluid retention
- nose bleed
- headache, dizziness, drowsiness
- feeling unusually weak or tired
- ear infections or pain
- skin infection
- viral infection, chickenpox
- short sightedness
- fever, cough, wheezing
- swollen runny eyes
- respiratory tract infections such as
  - inflammation of the sinuses (sinusitis)
  - sore throat and discomfort when swallowing (pharyngitis)
  - runny or blocked nose (rhinitis)
  - inflammation of the main air way to the lungs (bronchitis)
  - serious lung infection (pneumonia)
  - flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills
  - nasal congestion
- dental pain and/or infection.
- inflammation of the stomach and intestines, usually caused by a virus (gastroenteritis), symptoms include mild to severe nausea, vomiting, cramps, diarrhoea

**muscle or nerve problems:**

- muscle aches or cramps, joint pain
- decreased feeling or sensitivity, especially in the skin
- pins and needles

**stomach or bowel problems:**

- stomach pain
- nausea, vomiting
- diarrhoea
- indigestion
- dry mouth

The above list includes some side effects of your medicine. They are usually mild and short lived.

Tell your healthcare provider right away if you notice any of the following behaviour and mood-related changes:

- agitation, including aggressive behaviour and/or hostility
- tremor
- irritability, restlessness, feeling anxious or sleepy
- depression
- seeing, feeling or hearing things that are not there (also called hallucinations)
- dream abnormalities, difficulty sleeping
- sleep walking
- obsessive-compulsive symptoms

**Tell your doctor immediately if you notice any of the following:**

- skin rash or itchiness
- increased tendency to bleed (thrombocytopenia), bruising
- fast or irregular heartbeats, also called palpitations
- symptoms of liver disease such as nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine; elevation of liver enzymes
- suicidal thoughts and behavior
- severe upper stomach pain, often with nausea and vomiting
- presence of pus in urine
- trauma
- 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). This has been reported very rarely.

The above list includes serious side effects that may require medical attention.

If any of the following happens, tell your doctor immediately, or go to Accident and Emergency at the nearest hospital:

- swelling of the face, lips, mouth, throat or tongue which may cause difficulty in breathing or swallowing
- pinkish, itchy swellings on the skin, also called hives or nettlerash
- seizure

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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.

**Reporting of side effects**

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

**Storage and Disposal of AIRLUKAST TABLETS**

**Storage**

Store below 30°C, protect from light and moisture.

**Disposal**

Return any unused or expired medicine to your doctor, pharmacist or health care professional for safe disposal.

**Product description**

**What AIRLUKAST TABLETS looks like**

**AIRLUKAST TABLETS 10 mg**

Beige to light yellow coloured, rounded square, film-coated tablets, engraved with '10' on one side and scored on the other side.

**Ingredients**

- *Active ingredient:*

Montelukast Sodium Eq. to Montelukast 10 mg

- *Inactive ingredients:*

Lactose monohydrate, Microcrystalline cellulose, Hydroxypropyl cellulose, Croscarmellose sodium, Magnesium stearate, Opadry yellow

- *MAL No.*

**MAL11085001AZ**

**Manufacturer and Product Registration Holder**

RANBAXY (MALAYSIA) SDN. BHD.  
Lot 23, Bakar Arang Industrial Estate,  
08000 Sungai Petani, Kedah,  
Malaysia.

**Date of Revision:**

October 2022

**Serial No:** NPRA (R2/1)200923/528