

Aspira Oral Granules / Aspira Chewable Tablet / Aspira Tablet

Montelukast (4.0mg,5.0mg,10.0mg)

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What Aspira is used for

Aspira contains the active substances Montelukast sodium. It is used for the treatment of asthma in adults and children 12 months of age and older.

Aspira may also be used for relieving day and night symptoms of seasonal allergic rhinitis (hay fever) in adults and children 2 years of age and older.

How Aspira works

Aspira is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs. By blocking leukotrienes, Aspira improves asthma symptoms and helps control asthma. Aspira also improves hay fever symptoms.

Before you use Aspira

-When you must not use it

Do not take Aspira if you or your child is allergic to any medicine containing Montelukast or any of the other ingredients listed at the end of this leaflet.

-Before you start to use it

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

Oral Aspira is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you or your child. Always have your inhaled rescue medicine for asthma attacks with you.

Do 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.

Pregnancy and lactation

Discuss with your doctor or pharmacist first if you are pregnant or plan to get pregnant or breastfeeding.

-Taking other medicines

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

Tell your doctor or pharmacist if you are taking below medicines:

- Other medicine for treatment of asthma treatment and allergic rhinitis (hay fever)
- Paclitaxel (anti-cancer drug), rosiglitazone & repaglinide (antidiabetic drug)
- Gemfibrozil (use for lowering the lipid levels)
- Prednisone (use to suppress the immune system & decrease inflammation in condition such as asthma)
- Phenytoin and Phenobarbital (used for treatment of epilepsy)
- Rifampicin (used to treat tuberculosis and some other infections)

How to use Aspira

-How much to use

Montelukast should be taken once daily. For asthma, the dose should be taken in the evening. For allergic rhinitis, the time of administration may be individualized to suit patient needs. Patients with both asthma and allergic rhinitis should take only one tablet daily in the evening.

Montelukast tablets, chewable tablets, and oral granules can be taken with or without food.

No dosage adjustment is necessary for pediatric patients, for the elderly, for patients with renal insufficiency, or mild-to-moderate hepatic impairment, or for patients of either gender.

Adults 15 Years of Age and Older with Asthma and/or Seasonal Allergic Rhinitis

The dosage for adults 15 years of age and older is one 10-mg tablet daily.

Pediatric Patients 6 to 14 Years of Age with Asthma and/or Seasonal Allergic Rhinitis

The dosage for pediatric patients 6 to 14 years of age is one 5-mg chewable tablet daily.

Pediatric Patients 2 to 5 Years of Age with Asthma and/or Seasonal Allergic Rhinitis

The dosage for pediatric patients 2 to 5 years of age is one packet of 4-mg oral granules daily.

Pediatric Patients 12 months to 2 Years of Age with Asthma

The dosage for pediatric patients 12 months to 2 years of age is one packet of 4-mg oral granules daily.

Administration of oral granules :

Montelukast oral granules can be administered either directly in the mouth, or mixed with a spoonful of cold or room temperature soft food (e.g., applesauce) or dissolved in 1 teaspoonful (5 ml) of cold or room temperature baby formula or breast milk. The packet should not be opened until ready to use. After opening the packet, the full dose of Montelukast oral granules must be administered immediately (within 15 minutes). If mixed with food or dissolved in baby formula or breast milk, Montelukast oral granules must not be stored for future use. Montelukast oral granules are not intended to be dissolved in any liquid other than baby formula or breast milk for administration.

However, liquids may be taken subsequent to administration.

-When to use it

Use as directed by your doctor or pharmacist.

-How long to use it

Continue taking Aspira for as long as your doctor recommends.

-If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

-If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms included abdominal pain, sleepiness, thirst, headache, vomiting, and hyperactivity.

While you are using it

-Things you must do

You are advised to continue taking Montelukast even if the asthma is controlled, as well as during periods of worsening asthma.

If you experience any side effects, stop taking this medication immediately and consult your doctor/pharmacist.

Take your medicine exactly as your doctor or pharmacist has told you. Talk to your doctor or pharmacist if your symptoms do not improve. Your doctor or pharmacist will assess your condition and decide if you should continue taking this medicine.

-Things you must not do

Do not stop taking the medicines unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Aspira to anyone else even if they have the same symptoms or condition as you.

-Things to be careful of

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

Side Effects

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

Montelukast has been generally well tolerated. Side effects, which usually were mild, generally did not require discontinuation of therapy.

- Cardiovascular effects: palpitations, allergic granulomatosis angiitis (Systemic eosinophilia with vasculitis and a clinical presentation consistent with Churg-Strauss. Symptoms may include eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications and/or neuropathy)
- Skin and subcutaneous tissue disorders: angioedema, bruising, erythema nodosum, atopic dermatitis, eczema, infection of skin and/or subcutaneous tissue, rash, urticaria, erythema multiforme, and pruritus
- Gastrointestinal effects: abdominal pain, dental pain, diarrhea, gastroenteritis, indigestion, infection of tooth, nausea, pancreatitis, tonsillitis, vomiting, and dyspepsia
- Hematologic effects: blood coagulation disorder (increased bleeding tendency)
- Hepatic Effects: ALT/ AST levels raised, cholestatic hepatitis, hepatocellular and mixed-pattern liver injury
- Immunologic effects: hypersensitivity reactions, including anaphylaxis, varicella, and viral infection. Very rarely hepatic and eosinophilic infiltration
- Neurologic effects: asthenia, disorientated, dizziness, headache,

hyperactive behavior, hypesthesia, insomnia, paresthesia, seizure, sinus headache, drowsiness, and tremor

- Ophthalmic effects: conjunctivitis, and myopia
- Otic effects: otalgia, otitis, and otitis media
- Psychiatric effects: aggressive behavior, agitation, altered behavior, anxiety, depression, dream disorder, feeling nervous, hallucinations, irritability, nightmares, restlessness, sleep disorder, somnambulism, suicidal thinking and behavior (including suicide), hostility, anxiousness, disturbances in attention, memory impairment and tic
- Renal effects: pyuria and enuresis in children
- Respiratory effects: bronchitis, acute, cough, epistaxis, laryngitis, nasal congestion, nasal discharge, pharyngitis, pneumonia, respiratory tract infection, rhinitis, sinusitis, upper respiratory infection, wheezing and pulmonary eosinophilia
- Musculoskeletal and connective tissue disorders: arthralgia, and myalgia including muscle cramps
- Other: fatigue, fever, influenza, malaise, traumatic injury, edema and pyrexia
- Postmarketing experience: Blood and lymphatic system disorders: Thrombocytopenia

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

- Obsessive-compulsive 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.

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 [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Aspira**-Storage**

Keep your medicine in a safe place out of the reach and sight of children.

Do not store above 30°C. Store in the original package.

Do not take this medicine after the expiry date which is stated on the carton, after EXP.

-Disposal

Medicines should not be disposed of via wastewater or household water. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description**-What it looks like**

Aspira Oral Granules 4mg:

White free flowing granular powder

Aspira Chewable Tablet 5mg:

White to off-white, round, biconvex tablet with Pharmaniaga icon on one side and plain on the other

Aspira Tablet 10mg:

Beige, square shaped biconvex coated tablet with Pharmaniaga icon on one side and plain on the other

-Ingredients

Aspira Oral Granules 4mg

-Active ingredient(s) :

Each sachet contains Montelukast sodium 4.2mg (equivalent to Montelukast 4.0mg)

-Inactive ingredients :

Mannitol, Colloidal Silicon Dioxide, Hydroxypropyl Cellulose, Magnesium Stearate

Aspira Chewable Tablet 5mg

-Active ingredient(s) :

Each chewable tablet contains Montelukast sodium 5.19mg (equivalent to Montelukast 5.0mg)

-Inactive ingredients :

Pearlitol SD, Microcrystalline Cellulose 101, Hydroxypropyl Cellulose (Klucel EXF), Croscarmellose Sodium, Aspartame Powder, Cherry Flavour Powder, Magnesium Stearate, Purified Water

Aspira Tablet 10mg

-Active ingredient(s) :

Each tablet contains Montelukast sodium 10.4mg (equivalent to Montelukast 10.0mg)

-Inactive ingredients :

Microcrystalline Cellulose, Lactose Anhydrous, Lactose Monohydrate, Colloidal Silicon Dioxide, Hydroxypropyl Cellulose, Croscarmellose Sodium, Talc, Magnesium Stearate, Opadry Orange

-MAL Number(s):

Aspira Oral Granules 4mg:

MAL12095093AZ

Aspira Chewable Tablet 5mg:

MAL12085074AZ

Aspira Tablet 10mg:

MAL13085053AZ

Manufacturer

Pharmaniaga Manufacturing Berhad (198001006232),
11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650, Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

Product Registration Holder

Pharmaniaga Manufacturing Berhad (198001006232),
11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650, Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

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