

APO-MONTELUKAST TABLETS

Contains the active ingredient montelukast sodium

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking your medicine.

Ask your doctor or pharmacist if you do not understand anything or are worried about taking your medicine.

This leaflet answers some common questions about Montelukast.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. Some more recent information on the medicine may be available. Speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Keep this leaflet with the medicine.

You may want to read it again.

What this medicine is used for

Montelukast is used to treat:

- asthma, including preventing asthma symptoms during the day and night. It also prevents the narrowing of

airways triggered by exercise.

- seasonal and year-round allergies, including daytime and nighttime symptoms, including nasal congestion, runny nose, nasal itching, and sneezing; nasal congestion upon awakening, difficulty going to sleep, and nighttime awakenings; tearing, itchy, red, and puffy eyes.

Montelukast can be used in children 2 years of age and older, teenagers and adults.

Montelukast tablets are not used to treat an acute attack of asthma. If an acute attack occurs, follow your doctor's instructions for that situation.

Asthma is a lung disease and has the following characteristics:

- narrowed airways causing breathing to become difficult
- inflamed airways, which means the lining of airways become swollen
- sensitive airways that react to many things, such as cigarette smoke, pollen, or cold air.

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 allergies (also known as hay fever) are triggered by outdoor allergens such as airborne pollens from trees, grasses and weeds.

Year-round allergies may occur year-round and are generally triggered by indoor allergens such as dust mites, animal dander, and/or mould spores.

The daytime and nighttime symptoms of allergies typically may include:

- stuffy, runny, itchy nose
- sneezing
- watery, swollen, red, itchy eyes.

Montelukast belongs to a group of medicines called leukotriene receptor antagonists. It works by blocking substances in your lungs called leukotrienes that cause narrowing and swelling of airways. Blocking leukotrienes improves asthma symptoms and helps prevent asthma attacks. Leukotrienes also cause allergy symptoms. Blocking leukotrienes improves allergic rhinitis (seasonal and year-round, also known as outdoor and indoor nasal allergies).

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed montelukast for another reason.

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

There is no evidence that this medicine is addictive.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- you have an allergy to montelukast or any of the ingredients listed at the end of this leaflet
- the packaging is torn or shows signs of tampering
- the expiry date on the pack has passed.
If you take this medicine after the expiry date has passed, it may not work.

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

Do not give montelukast to children under 2 years of age. Safety and effectiveness in children younger than 2 years of age have not been studied.

Before you start to take it

Tell your doctor if:

- you are pregnant or intend to become pregnant.
Montelukast has not been studied in pregnant women.
- you are breast-feeding or plan to breast-feed.
It is not known if montelukast passes into breast milk.
- if you have or have had any medical conditions
- if you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell them before you take any montelukast.

Taking other medicines

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

Some medicines may affect the way other medicines work. In

general, montelukast does not interfere with other medicines that you may be taking. However, some medicines may affect how montelukast works, or montelukast may affect how your other medicines work.

How to use it

Take montelukast only when prescribed by your doctor.

For adults and teenagers 15 years and older, for the treatment of asthma, seasonal and year-round allergies, the dose is one 10 mg tablet taken daily.

For children 6 to 14 years old, for the treatment of asthma, seasonal and year round allergies, the dose is one 5 mg chewable tablet taken daily.

For children 2 to 5 years old, for the treatment of asthma, seasonal and year round allergies, the dose is one 4 mg chewable tablet taken daily.

Studies have shown that montelukast does not affect the growth rate of children.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How to take it

Montelukast comes as three types of tablets:

- 10 mg tablets for adults and teenagers 15 years and older
- 5 mg chewable tablets for children 6-14 years old
- 4 mg chewable tablets for children 2 -5 years old

Swallow the 10 mg tablet with a glass of water.

Chew the 4 mg or 5 mg chewable tablet thoroughly and swallow.

When to take it

For patients with asthma, take montelukast once a day in the evening.

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

For patients with allergic rhinitis, take montelukast once a day as prescribed by your doctor.

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

How long to take it for

Montelukast helps control your asthma. Therefore, montelukast must be taken every day.

Continue taking montelukast for as long as your doctor prescribes

Make sure you have enough to last over weekends and holidays.

If you forget to take it

Skip the dose you missed and take your next dose at bedtime as usual. Do not take a double dose to make up for the dose that you missed.

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

This may increase the chance of you getting an unwanted side effect.

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 or the National Poisons Information Centre (0800 POISON or 0800 764 766) 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 montelukast.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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.

While you are taking this medicine

Things you must do

Continue taking montelukast 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 montelukast, tell your doctor immediately.

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

If you experience behaviour and mood-related changes while taking montelukast, tell your doctor immediately.

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

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking montelukast.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking montelukast.

Things you must not do

Do not take your medicine to treat any other complaints unless your doctor or pharmacist tells you to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not stop taking your medicine, or change the dosage, without checking with your doctor.

Things to be careful of

Be careful while driving or operating machinery until you know how montelukast affects you.

Montelukast is not expected to affect your ability to drive a car or operate machinery.

Side effects

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

All medicines may have some unwanted side effects.

Sometimes they are serious, but most of the time, they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

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

Following is a list of possible side effects. Do not be alarmed by this list. You may not experience any of them.

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

- headache
- stomach pain
- thirst

In studies, these are the more common adverse effects of montelukast. For the most part these have been mild and occurred as often in patients treated with montelukast or placebo (a tablet containing no medicine).

Additionally, the following have been reported:

- upper respiratory infection
- increased bleeding tendency, low blood platelet count
- behaviour and mood related changes [agitation including aggressive behaviour or hostility, depression, disorientation, disturbances in attention, dream abnormalities, feeling anxious, hallucinations, insomnia, irritability, memory impairment, obsessive-compulsive symptoms, restlessness, sleep walking, suicidal thoughts and actions, tremor, uncontrolled muscle movements]
- dizziness, drowsiness, pins and needles/numbness
- palpitations
- nose bleed; swelling (inflammation) of the lungs,
- diarrhoea, dyspepsia, nausea, vomiting
- hepatitis
- bruising, rash, and itching
- joint pain, muscle aches and muscle cramps
- bedwetting in children
- weakness/tiredness
- swelling
- fever

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

- allergic reactions [including swelling of the face, lips, tongue, and/or throat (which may cause trouble breathing or swallowing), hives (severe and sudden onset of pinkish itchy swellings on the skin, also called nettle rash)],

- severe skin reactions that may occur without warning
- seizure, fit or convulsions.

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

Other side effects not listed above may also occur in some people.

Storage and disposal

Storage

Keep montelukast in its original packaging until it is time to take it.

If you take the tablets out of their original packaging they may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C. Protect it from light and moisture.

Do not store your medicine, or any other medicine, in the bathroom or near a sink.

Do not leave it on a window sill or in the car on hot days.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking this medicine or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Apo-Montelukast 4mg chewable tablets: Pink coloured, oval shaped, biconvex tablets, engraved with "APO" on one side and "M4" on the other side. The tablets may be mottled.

Apo-Montelukast 5mg chewable tablets: Pink coloured, round shaped, biconvex tablets, engraved with "APO" on one side and "M5" on the other side. The tablets may be mottled.

Available in blister pack of 4, 14, 28 tablets and bottles of 14, 28 and 100 tablets.

Apo-Montelukast 10mg tablets: Beige coloured, rounded square shaped, biconvex tablets, engraved with "APO" on one side and "M10" on the other side.

Available in blister pack of 4, 14 and 28 tablets.

*Not all presentations may be marketed.

Ingredients

Active Ingredient:

Each tablet contains either 4mg, 5mg and 10mg of montelukast sodium.

Apo-Montelukast 10mg tablet contains the following inactive excipients:

- Lactose anhydrous
- Microcrystalline cellulose
- Croscarmellose sodium
- Colloidal silicon dioxide
- Magnesium stearate
- Hypromellose
- Hyprollose
- Yellow iron oxide
- Red iron oxide
- Titanium dioxide

- Purified water

APO-Montelukast 10 mg tablets contain Lactose and are Gluten free

Apo-Montelukast 4mg and 5mg chewable tablets contain the following excipients:

- Mannitol
- Microcrystalline cellulose
- Croscarmellose sodium
- Aspartame
- Cherry flavour
- Euroxide Red iron oxide
- Magnesium stearate

APO-Montelukast 4mg and 5mg chewable tablets contain Aspartame and are Lactose and Gluten free.

Sponsor

Apotex NZ Ltd
32 Hillside Road
Wairau Valley, Auckland 0627

Telephone: (09) 444 2073
Fax: (09) 444 2951
E-mail:
NZcustomerservice@apotex.com

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