

APO-Montelukast

Contains the active ingredient montelukast (as montelukast sodium)

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before 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. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

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

What this medicine is used for

The name of your medicine is APO-Montelukast.

It contains the active ingredient montelukast (as montelukast sodium).

It is used to:

- prevent asthma symptoms, including those that occur during the day and at night-time
- prevent the narrowing of airways triggered by exercise
- seasonal allergic rhinitis (hay fever) symptoms.

Montelukast tablets are not used to treat an acute attack of asthma. If an acute attack occurs, follow your doctor's instructions for your reliever medicine, and keep taking your montelukast tablets each night or as prescribed.

As a preventive medicine for asthma, montelukast can be used alone or in combination with other preventive medicines, such as inhaled corticosteroids. Your doctor may reduce your dose of inhaled corticosteroid while you are taking montelukast.

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

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

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

How it works

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 allergic rhinitis symptoms. By blocking leukotrienes, montelukast improves seasonal allergic rhinitis symptoms.

There is no evidence that this medicine is addictive.

Use in children

Montelukast should not be used in children under 2 years of age.

Safety and effectiveness in children younger than 2 years of age have not been studied.

Before you take this medicine

When you must not take it

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

Do not take this medicine if you have had an allergic reaction to montelukast or any of the ingredients listed at the end of this leaflet. If you think you are having an allergic reaction, contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- The packaging is torn, shows signs of tampering or it does not look quite right.
- **The expiry date (EXP) printed on the pack has passed.**

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
2. You or your child have or have had any medical conditions.
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
4. You are currently breastfeeding or you plan to breastfeed. Do not take this medicine whilst breastfeeding until you and your

doctor have discussed the risks and benefits involved.

5. You are taking or are planning to take any other medicines, This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Taking other medicines

Some medicines may affect how montelukast works, or montelukast may affect how your other medicines work.

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

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

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

For patients with asthma and/or seasonal allergic rhinitis, take montelukast only when prescribed by your doctor.

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

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

For children 2 to 5 years old, the dosage is one 4 mg chewable tablet taken each day.

For children 6 to 14 years old, the dosage is one 5 mg chewable tablet taken each day.

For adults and teenagers 15 years and older, the dose is one 10 mg tablet taken each day.

How to take it

Chew the 4 mg or 5 mg chewable tablets thoroughly and swallow. Do not swallow chewable tablets whole.

Swallow the 10 mg tablet with a glass of water.

When to take it

Asthma:

Take your montelukast at bedtime each day.

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

Seasonal allergic rhinitis:

Take your montelukast once a day as prescribed by your doctor.

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

Asthma and seasonal allergic rhinitis:

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

It does not matter if you take it before, with or after food.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

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

If you forget to take it

Skip the missed dose and take your next dose as usual.

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

This may increase the chance of unwanted side effects.

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

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

The most common symptoms reported with overdose in adults and children include thirst, sleepiness, dilated pupils, hyperactivity, and stomach pain.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- your asthma gets worse while taking montelukast
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed

Go to your doctor regularly for a check-up.

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

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

If you have been prescribed the 10 mg tablets, do not take two 5 mg chewable tablets in its place. If you have been prescribed the 5 mg tablets, do not take half a 10 mg tablet in its place.

The different strength tablets may not have the same effect, as they are absorbed slightly differently in the body.

Do not:

- Take montelukast to relieve an acute asthma attack. In case of an acute asthma attack, follow your doctor's instructions on what reliever medicine to use.
- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking montelukast or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor or pharmacist if you notice any of the following.

This list includes the more common side effects. Mostly, these are mild:

- fluid retention
- nose bleed
- headache, dizziness, drowsiness

- feeling unusually weak or tired
- upper respiratory tract infection.

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.

Tell your doctor if you notice any of the following behaviour and mood-related changes:

- agitation, including aggressive behaviour and/or hostility
- tremor
- irritability, restlessness, feeling anxious
- depression
- disorientation
- disturbance in attention
- seeing, feeling or hearing things that are not there (also called hallucinations)
- dream abnormalities, difficulty sleeping
- sleep walking.

Tell your doctor immediately if you notice any of the following.

These may be serious side effects. You may need medical attention.

- skin rash or itchiness
- increased tendency to bleed, bruising
- fast or irregular heartbeats, also called palpitations
- swelling (inflammation) of the lungs
- 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
- suicidal thoughts and actions

If you experience any of the following, stop taking your

medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

- seizure

Other side effects not listed above may occur in some patients.

Tell your doctor if you notice any other effects.

Allergic reactions

If you think you are having an allergic reaction to montelukast, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

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

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place, away from light, where the temperature will stay below 25°C.

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. Heat and dampness can destroy some medicines.

Keep this medicine 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 they have passed their expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Montelukast looks like

4mg chewable tablet:

Pink coloured, oval shaped, biconvex tablets, engraved with "APO" on one side and "M 4" on the other side. The tablets may be mottled.

5 mg chewable tablet:

Pink coloured, round shaped, biconvex tablets, engraved with "APO" on one side and "M 5" on the other side. The tablets may be mottled.

10mg Tablet:

Beige coloured, rounded square shaped, biconvex film coated tablets, with engraved "APO" on one side and "M10" on the other side.

Blister packs of 28 tablets

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 4 mg, 5 mg or 10mg of montelukast (as montelukast sodium) as the active ingredient.

The 4mg and 5mg tablets also contains the following inactive ingredients:

- mannitol,
- microcrystalline cellulose,
- croscarmellose sodium,
- aspartame
- magnesium stearate,

- artificial cherry flavour
- iron oxide red

The 10mg tablets also contains the following inactive ingredients:

- anhydrous lactose
- microcrystalline cellulose
- croscarmellose sodium
- anhydrous colloidal silica
- magnesium stearate
- hypromellose
- hydroxypropylcellulose
- iron oxide yellow
- iron oxide red and titanium dioxide

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

The 10mg tablets contains lactose.

Australian Registration Numbers

APO-Montelukast 4 mg chewable tablet (Blister pack): AUST R 179118.

APO-Montelukast 4 mg chewable tablet (Bottle): AUST R 179111.

APO-Montelukast 5 mg chewable tablet (Blister pack): AUST R 179115.

APO-Montelukast 5 mg chewable tablet (Bottle): AUST R 179110.

APO-Montelukast 10 mg Tablet Blister pack: AUST R 170248

APO-Montelukast 10 mg Tablet Bottle: AUST R 170246

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

Apotex Pty Ltd is the licensee of the registered trademarks APO and APOTEX from the registered proprietor, Apotex Inc.

This leaflet was last updated in:
February 2015