

Montelukast APOTEX

Montelukast

Consumer Medicine Information

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

What is in this leaflet

This leaflet answers some common questions about this medicine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

Montelukast is used to prevent asthma symptoms, including those that occur during the day and at night-time. It also prevents the narrowing of airways triggered by exercise.

If you have seasonal allergic rhinitis (hay fever), montelukast also treats your allergic rhinitis symptoms.

Montelukast is 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 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.

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 include: stuffy, runny, itchy nose, sneezing, and 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

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

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

Your doctor may have prescribed montelukast for another reason.

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

This medicine is not addictive.

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

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- montelukast
- any of the ingredients 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

Do not give this medicine to a child under the age of 2 years.

Safety and effectiveness in children younger than 2 years have not been established.

In studies investigating the effect of montelukast on the growth rate of children, it was shown that montelukast did not affect the growth rate of children when given for up to 56 weeks in one study.

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

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 or your child have a condition called phenylketonuria – the 5 mg and 4 mg chewable tablets contain aspartame, corresponding to 0.842 mg phenylalanine in each 5 mg tablet and 0.674 mg in each 4 mg tablet
- you or your child have any other medical conditions

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Montelukast has not been studied in pregnant women.

It is not known if montelukast passes into breast milk.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

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 montelukast may interfere with each other.

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 this medicine.

How to take this medicine

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

They may differ from the information contained in this leaflet.

If you do not understand the directions, ask your doctor or pharmacist for help.

How much to take

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

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

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

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

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.

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 5 mg or 4 mg chewable tablets thoroughly and swallow.

When to take it

Take your medicine at about the same time each day.

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

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

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.

How long to take it

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

This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

Continue taking your medicine until you finish the pack.

Stop using this medicine when the redness and itching have gone.

If you forget to take it

If it is almost time to take 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 medicine as you would normally.

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 Poisons Information Centre (telephone 13 11 26) 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 of this medicine. 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 using 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 reliever

medicine to use to relieve the attack.

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

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all 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

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.

Do not take this medicine 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 or lower the dosage without checking with your doctor.

Side effects

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

Montelukast 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 lists 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 or drowsiness
- feeling unusually weak or tired
- upper respiratory tract infection
- bedwetting in children
- muscle aches or cramps, or joint pain
- decreased feeling or sensitivity, especially in the skin
- pins and needles
- stomach pain
- nausea or vomiting
- diarrhoea

The above list includes the more common side effects of your medicine.

Behaviour and mood-related changes have been reported in patients taking montelukast. If you or your child experience these changes while taking montelukast, tell your doctor.

Tell your doctor as soon as possible if you notice any of the following:

- agitation, including aggressive behaviour and/or hostility (such as temper tantrums in children)
- suicidal thoughts and actions
- tremors
- irritability or restlessness
- anxiousness or depression (sad mood)
- disorientation (inability to know correct time, place or person)
- disturbance in attention or memory impairment
- seeing, feeling or hearing things that are not there (also called hallucinations)
- insomnia, dream abnormalities or difficulty sleeping
- sleep walking
- stuttering
- uncontrolled muscle movements
- obsessive-compulsive symptoms

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

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

- skin rash or itchiness
- increased tendency to bleed or 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

- pinkish, itchy swellings on the skin (also called hives or nettle rash) – severe skin reactions that may occur without warning
- seizures
- symptoms of an allergic reaction including 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

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

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.

Some of these side effects (for example, low blood platelet count) can only be detected when your doctor does tests from time to time to check your progress.

Storage and Disposal

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out the blister pack, they may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store this 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 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 tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What Montelukast-APOTEX looks like

10 mg tablet

Beige coloured, rounded square, biconvex, film coated tablet debossed "M10" on one side and plain on other side. AUST R 184834.

5 mg chewable tablet

Pink coloured, mottled, round, biconvex, uncoated tablet, debossed "M5" on one side and plain on other side. AUST R 184824.

4 mg chewable tablet

Pink coloured, mottled, oval, biconvex, uncoated tablet, debossed "M4" on one side and plain on other side. AUST R 184831.

Pack size of 28 tablets.

Ingredients

This medicine contains either 4 mg, 5 mg or 10 mg of montelukast as the active ingredient.

This medicine also contains the following:

10 mg film coated tablets

- microcrystalline cellulose
- lactose monohydrate
- hypromellose
- croscarmellose sodium
- magnesium stearate
- hypromellose
- titanium dioxide
- macrogol 6000
- iron oxide red
- iron oxide yellow

5 mg and 4 mg chewable tablets

- mannitol

- microcrystalline cellulose
- croscarmellose sodium
- aspartame
- cherry flavour
- iron oxide red
- magnesium stearate

This medicine does not contain gluten, sucrose, tartrazine or any other azo dyes.

Distributor

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