

MONTELUKAST SANDOZ

(montelukast sodium) chewable and film-coated tablets

Consumer Medicine Information

WARNING: If you experience behaviour and mood-related changes including suicidal thoughts and actions while taking MONTELUKAST SANDOZ (see "Behavioural and mood related changes under Side Effects"), tell your doctor immediately.

What is in this leaflet

This leaflet answers some common questions about MONTELUKAST SANDOZ. 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 montelukast 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 MONTELUKAST SANDOZ is used for

MONTELUKAST SANDOZ 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 SANDOZ also treats your allergic rhinitis symptoms.

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

MONTELUKAST SANDOZ 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 SANDOZ each night or as prescribed.

As a preventive medicine for asthma, MONTELUKAST SANDOZ 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 SANDOZ.

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.

For further information about asthma, contact the Asthma Foundation in your state on 1800 645 130, or www.asthmaaustralia.org.au.

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

How MONTELUKAST SANDOZ 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.

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

Montelukast is not addictive.

Before you take MONTELUKAST SANDOZ

When you must not take it

Do not take MONTELUKAST SANDOZ 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 SANDOZ, talk to your doctor.

Do not give MONTELUKAST SANDOZ to children under 2 years of age.

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

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.

Before you start to take it

Tell your doctor if:

1. **you are pregnant or intend to become pregnant.** Montelukast has not been studied in pregnant women.
2. **you are breast-feeding or plan to breast-feed.** It is not known if montelukast passes into breast milk.
3. **you have or have had any medical conditions.**
4. **your child has 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.
5. **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 SANDOZ.

Taking other medicines

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

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.

How to take MONTELUKAST SANDOZ

How much to take

For patients with asthma and/or seasonal allergic rhinitis, take MONTELUKAST SANDOZ 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 SANDOZ once a day in the evening.

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

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 SANDOZ comes as three types of tablets:

- 10 mg film-coated 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 film-coated tablet with a glass of water.

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

When to take it

Asthma

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

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

How long to take it

MONTELUKAST SANDOZ helps control your asthma. Therefore MONTELUKAST SANDOZ must be taken every day. Continue taking MONTELUKAST SANDOZ for as long as your doctor prescribes.

If you forget to take it

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

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

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

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, if you think that you or anyone else may have taken too much MONTELUKAST SANDOZ.

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

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

While you are using MONTELUKAST SANDOZ

Things you must do

Continue taking MONTELUKAST SANDOZ 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 SANDOZ, tell your doctor immediately.

MONTELUKAST SANDOZ is not for the treatment of acute asthma attacks.

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

All thoughts of suicide must be taken seriously. If you experience behaviour and mood-related changes including suicidal thoughts while taking MONTELUKAST SANDOZ (see "Behavioural and mood related changes" under Side Effects), tell your doctor immediately.

In asthmatic patients treated with montelukast, very rare cases of a combination of allergic symptoms including a flu-like illness, pins and needles or numbness of arms or legs, and/or rash have been reported. Although it is unknown if montelukast can cause this condition, you must tell your doctor right away if you get one or more of these symptoms.

If you become pregnant while taking MONTELUKAST SANDOZ, 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 SANDOZ.

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 SANDOZ 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 give MONTELUKAST SANDOZ to anyone else, even if they have the same condition as you.

Side effects

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

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 treatment if you get some of the side effects.

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

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

- fluid retention;
- nose bleed;
- headache, dizziness, drowsiness;
- feeling unusually weak or tired;
- upper respiratory tract infection;
- bedwetting in children;
- **muscle or nerve problems:**
 - muscle aches or cramps, joint pain,
 - decreased feeling or sensitivity, especially in the skin,
 - pins and needles/numbness
- **stomach or bowel problems:**
 - stomach pain,
 - nausea, vomiting,
 - diarrhoea.

Behaviour and mood-related changes including suicidal thoughts and actions have been reported in patients taking MONTELUKAST SANDOZ. If you or your child experience these changes while taking MONTELUKAST SANDOZ, tell your doctor.

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

- agitation, including aggressive behaviour or hostility
- anxiousness, depression (sad mood);
- disorientation, dream abnormalities, hallucinations (seeing or hearing things that are not there).
- insomnia, irritability, restlessness, sleep walking.;
- stuttering
- tremors
- disturbance in attention, memory impairment
- Uncontrolled muscle movements

- Obsessive-compulsive symptoms

These are usually mild side effects of MONTELUKAST SANDOZ.

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

- suicidal actions and thoughts;
- skin rash or itchiness;
- increased tendency to bleed, bruising;
- fast or irregular heart-beats, 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.

These may be serious side effects.

You may need urgent medical attention. Serious side effects are rare.

If any of the following happen, stop taking MONTELUKAST SANDOZ and tell your doctor immediately or go to accident and emergency at your 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 nettle rash, severe skin reactions that may occur without warning;
- seizure.

These may be serious side effects. If you have them, you may be having a serious allergic reaction to MONTELUKAST SANDOZ. You may need urgent medical attention.

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

Tell your doctor if you notice any other effects.

After using MONTELUKAST SANDOZ

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 this medicine in a cool dry place, away from light, where the temperature stays below 25°C.

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

Do not leave it in the car or on window sills.

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 the tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Australia

Telephone: 1800 726 369

This leaflet was prepared in February 2025.

Product description

What it looks like

MONTELUKAST SANDOZ comes as three types of tablets:

- 10 mg tablet: Beige coloured, rounded square, biconvex, film-coated tablet debossed with “M10” on one side and plain on the other side.
- 5 mg chewable tablet: Pink coloured, mottled, round, biconvex, uncoated tablet, debossed with “M5” on one side and plain on the other side.
- 4 mg chewable tablet: Pink coloured, mottled, oval, biconvex, uncoated tablet, debossed with “M4” on one side and plain on the other side.

MONTELUKAST SANDOZ comes in blister packs of 28 tablets.

Ingredients

Active ingredient

- 10 mg film-coated tablet contains 10 mg montelukast (as sodium).
- 5 mg chewable tablet contains 5 mg montelukast (as sodium).
- 4 mg chewable tablet contains 4 mg montelukast (as sodium).

Inactive ingredients

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 501027 AP0551 (PI 107148)
- iron oxide red
- magnesium stearate

The 10 mg film-coated tablets contain lactose.

The 5 mg and 4 mg chewable tablets contain aspartame and phenylalanine.

The 10 mg film coated tablets, and 5 mg and 4 mg chewable tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

MONTELUKAST SANDOZ® 4 mg:

AUST R 184832

MONTELUKAST SANDOZ® 5 mg:

AUST R 184833

MONTELUKAST SANDOZ® 10 mg:

AUST R 184830

Distributor

Sandoz Pty Ltd
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