

Montelukast Sodium (4mg Chewable Tablets, 5mg Chewable Tablets, 10mg Film-Coated Tablets)

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What is MONTELUKAST SANDOZ used for

You have been prescribed Montelukast Sandoz for:

- Asthma, including preventing your asthma symptoms during the day and night.
- Allergic rhinitis, including daytime and nighttime symptoms: nasal congestion, runny nose, nasal itching, and sneezing; tearing, itchy, red, and puffy eyes.

How MONTELUKAST SANDOZ works

Montelukast Sandoz is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in your lungs. Blocking leukotrienes improves asthma symptoms and helps prevent asthma attacks. Leukotrienes also cause allergy symptoms. Blocking leukotrienes improves allergic rhinitis (seasonal and perennial, also known as outdoor and indoor nasal allergies).

Before you use MONTELUKAST SANDOZ

- When you must not use it
 - If you are allergic (hypersensitive) to montelukast, or to any of the ingredients.
- Before you start use it
 - Tell your doctor (or health care provider) about any medical problems or allergies you had.
 - The chewable tablets

contain Aspartame, hence is unsuitable for patients with phenylketonuria.

Use in children

For children 6 to 14 years old, Montelukast Sandoz 5 mg chewable tablets are available.

For children 2 to 5 years old, Montelukast Sandoz 4 mg chewable tablets and montelukast 4 mg oral granules are available.

For children 12 months to 2 years old with asthma, montelukast 4 mg oral granules are available.

Safety and effectiveness of Montelukast Sandoz in children less than 12 months old have not been established.

Pregnancy and breast-feeding

Women who are pregnant or intend to become pregnant should consult their doctor before taking Montelukast Sandoz.

It is not known if Montelukast Sandoz appears in breast milk. You should consult your doctor before taking Montelukast Sandoz if you are breast-feeding or intend to breast-feed.

Ask your doctor or pharmacist for advice before taking any medicine.

- Taking other medicines

In general, Montelukast Sandoz does not interfere with other medicines that you may be taking. However, some medicines may affect how Montelukast Sandoz works, or Montelukast Sandoz may affect how your other medicines work. It is important to tell your doctor about all drugs that you are using or plan to use, including those obtained without a prescription. Ask your doctor if you are not sure.

How to use MONTELUKAST SANDOZ

- How much to use

Always take your medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- The dose for adults and adolescents 15 years and older for the treatment of asthma and/or allergic rhinitis is one 10 mg tablet daily.
- The dose for children 6 to 14 years old for the treatment of asthma and/or allergic rhinitis is one 5 mg chewable tablet daily.
- The dose for children 2 to 5 years old for the treatment of asthma and/or allergic rhinitis is one 4 mg chewable tablet daily or one packet of 4 mg oral granules daily.
- The dose for children 12 months to 2 years old for the treatment of asthma is one packet of 4 mg oral granules daily.

Take Montelukast Sandoz once a day as your doctor has prescribed.

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

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

It is important to continue taking Montelukast Sandoz for as long as your doctor prescribes it in order to maintain control of your condition.

- When to use it

Always take this medicine exactly as your doctor told you. Please ask your doctor or pharmacist if you are not sure.

- How long to use it

It is important to take your medicine every day. Always consult your doctor, if you wish to stop taking this medicine. Even if you feel well, it may be necessary to continue taking this medicine.

If you have any further questions on the use of this product, ask your doctor or pharmacist

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

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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 nearest emergency department if 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.

While you are using it

- *Things you must do*

- Take your medicine exactly as your doctor has told you.
- If asthma symptoms get worse, you should contact your doctor immediately.
- Montelukast Sandoz is not for the treatment of acute asthma attacks. If an attack occurs, you or your child should follow the instructions your doctor has given you for that situation.
- Behavior and mood-related changes have been reported in patients taking Montelukast Sandoz. If you experience these changes while taking this medicine, tell your doctor.
- Tell your doctor immediately if you become pregnant while taking this medication.

- *Things you must not do*

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Montelukast Sandoz to anyone else, even if they have the same symptoms or condition as you.
- 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.

- *Things to be careful of*

Driving and using machines

Montelukast Sandoz is not expected to affect your ability to drive a car or

operate machinery. However, in very rare cases, drowsiness and dizziness have been reported.

Side effects

Like all medicines, Montelukast Sandoz can cause side effects, although not everybody gets them. Montelukast Sandoz is generally well-tolerated. Side effects reported were abdominal pain, headache, diarrhea, hyperactivity, wheezing, scaly and itchy skin, and rash.

Additionally, the following have been reported:

- upper respiratory infection
- increased bleeding tendency
- allergic reactions [including swelling of the face, lips, tongue, and/or throat (which may cause trouble breathing or swallowing), hives, rash, and itching]
- behavior and mood related changes [agitation including aggressive behavior or hostility, depression, disorientation, disturbance in attention, dream abnormalities, feeling anxious, hallucinations, insomnia, irritability, memory impairment, restlessness, suicidal thoughts and actions]
- dizziness, drowsiness, pins and needles/numbness, seizure
- palpitations
- nose bleed
- diarrhea, dyspepsia, nausea, vomiting
- hepatitis
- bruising
- joint pain, muscle aches and muscle cramps
- weakness/tiredness
- fever

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

- Obsessive-compulsive symptoms

Tell your doctor or pharmacist if you develops any unusual symptom, or if any known symptom continues or worsens. 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 MONTELUKAST SANDOZ

- *Storage*

Keep out of the reach and sight of children.

Do not use your medicine after the expiry date.

Store below 30°C in the original package in order to protect from moisture.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. 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*

MONTELUKAST SANDOZ 4 MG CHEWABLE TABLET:

Oval pink tablet to slightly speckled pink tablet with odour of cherry, encoded 4 on one side.

MONTELUKAST SANDOZ 5 MG CHEWABLE TABLET:

Round pink tablet to slightly speckled pink tablet with odour of cherry, encoded 5 on one side.

MONTELUKAST SANDOZ 10 MG FILM-COATED TABLET:

Beige, round, biconvex, coated tablet (plain on both sides).

- *Ingredients*

Active ingredient

Montelukast Sandoz contains montelukast sodium as the active ingredient.

Each 10 mg film-coated tablet contains 10 mg montelukast.

MONTELUKAST SANDOZ[®]

Consumer Medication Information Leaflet (RiMUP)

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Each 5 mg chewable tablet
contains 5 mg montelukast.
Each 4 mg chewable tablet
contains 4 mg montelukast.

Inactive ingredients

MONTELUKAST SANDOZ 4 MG
and 5 MG CHEWABLE TABLET:

- hydroxypropylcellulose
- aspartame
- ferric oxide red
- flavor (cherry flavour, cherry
duarome)
- mannitol
- magnesium stearate
- croscarmellose sodium
- cellulose microcrystalline

MONTELUKAST SANDOZ 10 MG
FILM-COATED TABLET

- lactose monohydrate
- hydroxypropylcellulose
- cellulose microcrystalline
- croscarmellose sodium
- magnesium stearate
- opadry beige II

- **MAL numbers**

Montelukast Sandoz 4 mg Chewable
Tablet: MAL15015050AZ

Montelukast Sandoz 5 mg Chewable
Tablet: MAL15015051AZ

Montelukast Sandoz 10 mg Film
Coated Tablet: MAL15125047AZ

Manufacturer

Lek S.A.
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95-010 Strykow, Poland

Product Registration Holder

Sandoz Products Malaysia Sdn. Bhd.
3A-2 & 3A-3, Level 3A, Menara
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Date of revision

Jul 2026

Serial number

NPRA(R2/3)230207/1008