

1. NAME OF THE MEDICINAL PRODUCT

Montelukast Sandoz 4 mg Chewable Tablet.
Montelukast Sandoz 5 mg Chewable Tablet.
Montelukast Sandoz 10 mg Film-coated Tablet.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Montelukast Sandoz 4 mg Chewable Tablet

Each chewable tablet contains montelukast sodium equivalent to 4 mg of montelukast.
Excipient: Aspartame 0.96 mg per tablet.

Montelukast Sandoz 5 mg Chewable Tablet

Each chewable tablet contains montelukast sodium equivalent to 5 mg of montelukast.
Excipient: Aspartame 1.20 mg per tablet.

Montelukast Sandoz 10 mg film-coated tablet

One film-coated tablet contains montelukast sodium equivalent to 10 mg montelukast.
Excipient: Lactose 89.10 mg per tablet.

For a full list of excipients, see 6.1.

3. PHARMACEUTICAL FORM

Montelukast Sandoz 4 mg Chewable Tablet

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

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

Film-coated tablet.

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

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the prophylaxis and chronic treatment of asthma in adults and pediatric patients 12 months of age and older.

Montelukast is indicated in adults and pediatric patients 2 years of age and older for the relief of daytime and nighttime symptoms of seasonal allergic rhinitis.

4.2 Posology and method of administration

Recommended Dosage

Montelukast should be taken once daily. For asthma, the dose should be taken in the evening. For allergic rhinitis, the time of administration may be individualized to suit patient needs.

Patients with both asthma and allergic rhinitis should take only one dose daily in the evening.

Adults 15 Years of Age and Older with Asthma and/or Seasonal Allergic Rhinitis

The dosage for adults 15 years of age and older is one 10 mg tablet daily.

Pediatric Patients 6 to 14 Years of Age with Asthma and/or Seasonal Allergic Rhinitis

The dosage for pediatric patients 6 to 14 years of age is one 5 mg chewable tablet daily.

Pediatric Patients 2 to 5 Years of Age with Asthma and/or Seasonal Allergic Rhinitis

The dosage for pediatric patients 2 to 5 years of age is one 4 mg chewable tablet daily or one packet of 4 mg oral granules daily.

Pediatric Patients 12 months to 2 Years of Age with Asthma

The dosage for pediatric patients 12 months to 2 years of age is one packet of 4 mg oral granules daily.

General Recommendations

The therapeutic effect of Montelukast on parameters of asthma control occurs within one day. Montelukast tablets, chewable tablets and oral granules can be taken with or without food. Patients should be advised to continue taking Montelukast while their asthma is controlled, as well as during periods of worsening asthma.

No dose adjustment is necessary for pediatric patients, for the elderly, for patients with renal insufficiency, or mild-to-moderate hepatic impairment, or for patients of either gender.

Montelukast is a long term-controller medication which should not be substituted for short acting beta-agonists. It is effective alone or in combination with other prophylactic agent.

Montelukast is a preventive agent, which should be used in addition to other drugs for the management of asthma.

Therapy with Montelukast in Relation to Other Treatments for Asthma

Montelukast can be added to a patient's existing treatment regimen.

Reduction in Concomitant Therapy:

Bronchodilator Treatments: Montelukast can be added to the treatment regimen of patients who are not adequately controlled on bronchodilator alone. When a clinical response is evident (usually after the first dose), the patient's bronchodilator therapy can be reduced as tolerated.

Inhaled Corticosteroids: Treatment with Montelukast provides additional clinical benefit to patients treated with inhaled corticosteroids. A reduction in the corticosteroid dose can be made as tolerated. The dose should be reduced gradually with medical supervision. In some patients, the dose of inhaled corticosteroids can be tapered off completely. Montelukast should not be abruptly substituted for inhaled corticosteroids.

Mode of Administration

Oral.

4.3 Contraindications

Hypersensitivity to montelukast or to any of the excipients.

4.4 Special warnings and precautions for use

The efficacy of oral Montelukast for the treatment of acute asthma attacks has not been established. Therefore, oral Montelukast should not be used to treat acute asthma attacks. Patients should be advised to have appropriate rescue medication available.

While the dose of concomitant inhaled corticosteroid may be reduced gradually under medical supervision, Montelukast should not be abruptly substituted for inhaled or oral corticosteroids.

Neuropsychiatric events (e.g., agitation, aggression, anxiousness, dream abnormalities, hallucinations, depression, disorientation, insomnia, irritability, restlessness, suicidal thinking and behavior (including suicide), tremor have occurred. Since other factors may have contributed to these events, it is not known if they are related to Montelukast. Physicians should discuss these adverse experiences with their patients and/or caregivers. Patients and/or caregivers should be instructed to notify their physician if these changes occur.

The reduction in systemic corticosteroid dose in patients receiving anti-asthma agents including leukotriene receptor antagonists has been followed in rare cases by the occurrence of one or more of the following: eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy sometimes diagnosed as Churg-Strauss syndrome, a systemic eosinophilic vasculitis. Although a causal relationship with leukotriene receptor antagonism has not been established, caution and appropriate clinical monitoring are recommended when systemic corticosteroid reduction is considered in patients receiving Montelukast.

Patients with known aspirin sensitivity should continue avoidance of aspirin or non-steroidal anti-inflammatory agents while taking Montelukast.

Although Montelukast is effective in improving airway function in asthmatics with documented aspirin sensitivity, it has not been shown to truncate bronchoconstrictor response to aspirin and other documented aspirin sensitivity.

The film-coated tablet contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

The chewable tablets contains Aspartame, therefore is unsuitable in patients with phenylketonuria.

4.5 Interactions with other medicinal products and other forms of interaction

Montelukast may be administered with other therapies routinely used in the prophylaxis and chronic treatment of asthma, and in the treatment of allergic rhinitis.

The recommended clinical dose of montelukast did not have clinically important effects on the pharmacokinetics of the following medicinal products: theophylline, prednisone, prednisolone, oral contraceptives (ethinyl estradiol/norethindrone 35/1), terfenadine, digoxin and warfarin.

Montelukast is not anticipated to alter the metabolism of drugs metabolized by this enzyme (e.g., paclitaxel, rosiglitazone, repaglinide).

Concurrent use of gemfibrozil and montelukast may result in elevated montelukast plasma concentrations.

Concurrent use of prednisone and montelukast may result in severe peripheral edema.

Concurrent use of montelukast and repaglinide may result in increased repaglinide plasma concentrations.

Montelukast is metabolised by CYP 3A4, caution should be exercised, particularly in children, when montelukast is co-administered with inducers of CYP 3A4, such as phenytoin, phenobarbital and rifampicin.

Concurrent use of montelukast and phenobarbital may result in decreased bioavailability of montelukast.

Concurrent use of montelukast and rifampin may result in decreased bioavailability of montelukast.

Clinically important drug interactions with less potent inhibitors of CYP 2C8 (e.g., trimethoprim) are not anticipated. Co-administration of montelukast with itraconazole, a strong inhibitor of CYP 3A4, resulted in no significant increase in the systemic exposure of montelukast.

4.6 Pregnancy and lactation

Pregnancy

The safety and efficacy of montelukast have not been determined in pregnant women. Rarely, congenital limb defects have been reported during post-marketing surveillance; however, causality has not been established. Due to the lack of human safety information, montelukast should be used in pregnant women only if the potential benefit outweighs the potential risk to the fetus.

Lactation

Lactation studies with montelukast in humans have not been conducted. Montelukast is excreted into the milk of lactating rats. Until further data are available, caution is advised if montelukast is used in nursing women.

Available evidence and/or expert consensus is inconclusive or is inadequate for determining infant risk when used during breastfeeding. Weigh the potential benefits of drug treatment against potential risks before prescribing this drug during breastfeeding.

4.7 Effects on ability to drive and use machines

Montelukast is not expected to affect a patient's ability to drive a car or operate machinery. However, in very rare cases, individuals have reported drowsiness or dizziness.

4.8 Undesirable effects

Montelukast has been generally well tolerated. Side effects, which usually were mild, generally did not require discontinuation of therapy.

Cardiovascular Effects: palpitations, allergic granulomatosis angiitis (Systemic eosinophilia with vasculitis and a clinical presentation consistent with Churg-Strauss. Symptoms may include eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications and/or neuropathy)

Skin and subcutaneous tissue disorders: angioedema, bruising, erythema nodosum, atopic dermatitis, eczema, infection of skin and/or subcutaneous tissue, rash, urticaria, pruritus, erythema multiforme

Gastrointestinal Effects: abdominal pain, dental pain, diarrhea, gastroenteritis, indigestion, infection of tooth, nausea, pancreatitis, tonsillitis, vomiting, dry mouth

Hematologic Effects: blood coagulation disorder (increased bleeding tendency)

Hepatic Effects: ALT/ AST levels raised, hepatitis (including cholestatic, hepatocellular and mixed pattern liver injury)

Immunologic Effects: hypersensitivity reactions, including anaphylaxis, varicella, viral infection, hepatic eosinophilic infiltration

Neurologic Effects: asthenia, disorientated, dizziness, headache, hyperactive behavior, hypoesthesia, insomnia, paresthesia, seizure, sinus headache, drowsiness, and tremor

Ophthalmic Effects: conjunctivitis, myopia

Otic Effects: Otagia, Otitis, Otitis media

Psychiatric Effects: aggressive behavior or hostility, agitation, altered behavior, anxiety, depression, dream disorder, feeling nervous, hallucinations, nightmares, insomnia, sleep disorder, somnambulism, psychomotor hyperactivity (including irritability, restlessness, tremor), disorientation, suicidal thinking and behavior (including suicide), disturbance in attention, memory impairment

Renal Effects: pyuria

Respiratory Effects: upper respiratory infection, bronchitis, acute, cough, epistaxis, laryngitis, nasal congestion, nasal discharge, pharyngitis, pneumonia, respiratory tract infection, rhinitis, sinusitis, upper respiratory infection, wheezing, Churg-Strauss Syndrome (CSS), pulmonary eosinophilia

Musculoskeletal and connective tissue disorders: arthralgia, myalgia including muscle cramps

Other: fatigue, fever, influenza, malaise, traumatic injury, oedema

Post-marketing Experience

Blood and lymphatic system disorders: thrombocytopenia

Psychiatric disorders: obsessive-compulsive symptoms

4.9 Overdose

Symptoms

Symptoms included abdominal pain, somnolence, thirst, headache, vomiting, and psychomotor hyperactivity.

Treatment

Treatment is symptomatic and supportive. Treatment may include removal of unabsorbed material from the gastrointestinal tract, clinical monitoring and supportive therapy if required.

It is not known if montelukast can be removed by peritoneal dialysis or hemodialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Montelukast is a selective and active leukotriene receptor antagonist. Montelukast inhibits bronchoconstriction due to antigen challenge. Montelukast is a selective leukotriene receptor antagonist of the cysteinyl leukotriene CysLT₁ receptor. The cysteinyl leukotrienes (LTC₄, LTD₄, LTE₄) are products of arachidonic acid metabolism that are released from various cells, including mast cells and eosinophils. They bind to cysteinyl leukotriene receptors (CysLT) found in the human airway. Binding of cysteinyl leukotrienes to leukotriene receptors has been correlated with the pathophysiology of asthma, including airway edema, smooth muscle contraction, and altered cellular activity associated with the inflammatory process, factors that contribute to the signs and symptoms of asthma.

It binds to cysteinyl leukotrienes (CysLT) type-1 receptors found in human airway (smooth muscle cells and macrophages), which prevents airway edema, smooth muscle contraction and other respiratory inflammation. The leukotrienes are also released from the nasal mucosa after allergen exposure where montelukast sodium may inhibit symptoms of allergic rhinitis.

Montelukast binding to the CysLT1 receptor is high-affinity and selective, preferring the CysLT1 receptor to other pharmacologically important airway receptors, such as the prostanoid, cholinergic, or beta-adrenergic receptor. Montelukast inhibits physiologic actions of LTD4 at the CysLT1 receptors, without any agonist activity.

Montelukast causes bronchodilation within 2 hours of oral administration; these effects were additive to the bronchodilation caused by a beta-agonist.

5.2 Pharmacokinetic properties

Absorption

Montelukast is rapidly and nearly completely absorbed following oral administration. Peak plasma concentrations of montelukast occur 2 to 4 hours after oral doses. The mean oral bioavailability is 64% to 73%. The oral bioavailability and Cmax are not influenced by a standard meal.

Distribution

Montelukast is more than 99% bound to plasma proteins. The steady-state volume of distribution of montelukast averages 8 to 11 liters. Studies in rats with radiolabeled montelukast indicate minimal distribution across the blood-brain barrier.

Metabolism

Montelukast is extensively metabolized in the liver by cytochrome P450 isoenzymes, mainly by CYP2C8 and to a lesser extent by CYP3A4 and CYP2C9. Therapeutic plasma concentrations of montelukast do not inhibit cytochromes P450 3A4, 2C9, 1A2, 2A6, 2C19, or 2D6.

Elimination

The plasma clearance of montelukast averages 45 mL/min in healthy adults.

Montelukast and its metabolites are excreted principally in the faeces via the bile.

Elimination Half-life: 2.7 to 5.5 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Montelukast Sandoz 10 mg Film Coated Tablet

Lactose monohydrate
Hydroxypropylcellulose
Cellulose, microcrystalline
Croscarmellose sodium
Magnesium stearate
Opadry Beige II

Montelukast Sandoz 5 mg Chewable Tablet

Hydroxypropylcellulose
Aspartame
Ferric oxide, red
Flavour (Cherry Flavour, Cherry Duarome)
Mannitol
Magnesium stearate
Croscarmellose sodium
Cellulose microcrystalline

Montelukast Sandoz 4 mg Chewable Tablet

Hydroxypropylcellulose
Aspartame
Ferric oxide, red
Flavour (Cherry Flavour, Cherry Duarome)
Mannitol
Magnesium stearate
Croscarmellose sodium
Cellulose microcrystalline

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Please refer to outer carton for expiry date.

6.4 Special precautions for storage

Store below 30°C.

Store in the original package in order to protect from light and moisture.

6.5 Presentation

Montelukast Sandoz 4 mg Chewable Tablet

Packaged in aluminium/aluminium blister.

Pack sizes: 28, 30 and 100 tablets.

Montelukast Sandoz 5 mg Chewable Tablet

Packaged in aluminium/aluminium blister.

Pack sizes: 28, 30 and 100 tablets.

Montelukast Sandoz 10 mg Film-coated Tablet

Packaged in OPA/Alu/PVC blister.

Pack sizes: 28, 30 and 100 tablets.

Not all pack sizes will be marketed.

7. PRODUCT REGISTRATION HOLDER

Sandoz Products Malaysia Sdn. Bhd.

3A-2 & 3A-3, Level 3A, Menara KEN TTDI,

No. 37, Jalan Burhanuddin Helmi, Taman Tun Dr Ismail,

60000 Kuala Lumpur, Malaysia

8. DATE OF REVISION OF THE TEXT

Jul 2026