

Important information. Please read carefully.



# ALTRA™

Montelukast

Film-Coated Tablet 10mg  
Chewable Tablet 4mg & 5mg

## COMPOSITION

Altra Tablet 10mg: Each film-coated tablet contains 10mg Montelukast (as Montelukast Sodium).

Altra Chewable Tablet 5mg: Each chewable tablet contains 5mg Montelukast (as Montelukast Sodium).

Altra Chewable Tablet 4mg: Each chewable tablet contains 4mg Montelukast (as Montelukast Sodium).

## PHARMACODYNAMICS

Montelukast is a selective and competitive antagonist of the leukotriene C<sub>4</sub>, D<sub>4</sub>, and E<sub>4</sub> receptors, stimulation of which by circulating leukotrienes is thought to play a role in the pathogenesis of asthma.

The drug suppresses both early and late bronchoconstrictor responses to inhaled antigens and irritants, but is not suitable for the management of acute attacks of asthma.

## PHARMACOKINETICS

Peak plasma concentrations of montelukast are achieved in 3 to 4 hours after oral doses. The mean oral bioavailability is 64%.

Montelukast is more than 99% bound to plasma proteins. It is extensively metabolised in the liver by cytochrome P450 isoenzymes CYP3A4, CYP2A6, and CYP2C9, and is excreted principally in the faeces via the bile.

## INDICATIONS

Altra Tablet 10mg:

- Chronic and prophylaxis treatment of asthma in adults
- Symptomatic relief of seasonal allergic rhinitis in adults

Altra Chewable Tablet 4mg & 5mg:

- Chronic and prophylaxis treatment of asthma in adults and children 2 years old and above.
- Symptomatic relief of seasonal allergic rhinitis in adults and children 2 years old and above.

## DOSAGE AND ADMINISTRATION

To be administered orally. Once daily in the evening.

*Patients with asthma and/or seasonal allergic rhinitis*

- Adults 15 years old and above – one film-coated tablet (10mg) daily.
- Children 6 to 14 years old – one chewable tablet (5mg) daily.
- Children 2 to 5 years old – one chewable tablet (4mg) daily.

No dosage 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.

## CONTRAINDICATIONS

Hypersensitivity to any component of this product.

## WARNING AND PRECAUTIONS

- Montelukast is not to be used for acute asthma attacks.
- Montelukast should not be abruptly substituted for inhaled or oral corticosteroids.
- 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.
- Patients with known aspirin sensitivity should continue to avoid aspirin or non-steroidal anti-inflammatory agents while taking montelukast.
- Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine (for Altra Tablet 10mg only).

## DRUG INTERACTIONS

Montelukast may be administered with other therapies routinely used in the prophylaxis, and chronic treatment of asthma and in the treatment of allergic rhinitis, such as theophylline, prednisone, prednisolone, oral contraceptives, terfenadine, digoxin and warfarin.

Caution should be exercised when potent inducers of cytochrome P450 isoenzyme CYP3A4, such as phenytoin, phenobarbital and rifampicin are given with montelukast.

## PREGNANCY AND LACTATION

Montelukast may be used during pregnancy and lactation if it is considered to be clearly essential.

## SIDE EFFECTS

Side effects with montelukast are such as headache, respiratory tract infection, gastrointestinal disturbances, thirst, dry mouth, diarrhoea, dyspepsia, nausea, vomiting, generalized and abdominal pain, arthralgia, and myalgia.

Malaise, fever, insomnia, dizziness, sedation, palpitation, increased sweating, epistaxis, tremor, chest pain, depression, hallucinations, paraesthesia, hypoesthesia, suicidal thoughts and behavior, nightmares, anxiousness, agitation, aggression and seizures are reported too.

Hypersensitivity reactions found are anaphylaxis, angioedema, rashes, pruritus and urticaria.

Hepatic disorders including elevated liver enzyme values and rarely symptomatic hepatitis or hyperbilirubinaemia have occurred.

There have been rare reports of agranulocytosis, bleeding, bruising, oedema; and very rarely Churg-Strauss syndrome.

## Postmarketing Experience

Blood and lymphatic system disorders : thrombocytopenia  
Psychiatric disorders: obsessive-compulsive symptoms

## SYMPTOMS AND TREATMENT FOR OVERDOSAGE

No specific information is available on the treatment of overdosage with montelukast.

It is not known whether montelukast is dialysable by peritoneal- or haemodialysis.

## SHELF-LIFE

The expiry date is indicated on the packaging.

## STORAGE CONDITION

Store below 30°C. Protect from light and moisture.

## PRODUCT DESCRIPTION

*Altra Tablet 10mg*

Peach, round normal convex film-coated tablet, with "M" marking on one side and plain on reverse.

Available as blister strips of 10's in packing of 30 tablets per box.

*Altra Chewable Tablet 5mg*

Pink, round, normal convex, engraved "XSP" logo on one side and plain on the other.

Available as blister strips of 10's in packing of 30 tablets per box.

*Altra Chewable Tablet 4mg*

Pink, round, normal convex, engraved "M" logo on one side and plain on the other.

Available as blister strips of 10's in packing of 30 tablets per box.

## KEEP OUT OF REACH OF CHILDREN/ JAUHI DARI KANAK-KANAK

For further information, please consult your pharmacist or physician.

Revision Date: 19-Feb-2021

Manufacturer and Product Registration Holder

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