

Ontel

(Montelukast Sodium)
Tablets / Chewable Tablets

4mg	٢٠٠ ملي گرام
5mg	٥٠٠ ملي گرام
10mg	١٠٠٠ ملي گرام

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DESCRIPTION

Montelukast sodium, the active ingredient in **Ontel**, is a selective and orally active leukotriene receptor antagonist that inhibits the cysteinyl leukotriene CysLT₁ receptor.

Montelukast sodium is a hygroscopic, white to off-white powder.

CLINICAL PHARMACOLOGY

Mechanism of Action

The cysteinyl leukotrienes (LTC₄, LTD₄, LTE₄) are products of arachidonic acid metabolism and are released from various cells, including mast cells and eosinophils. These eicosanoids bind to cysteinyl leukotriene (CysLT) receptors. The CysLT type-1 (CysLT₁) receptor is found in the human airway (including airway smooth muscle cells and airway macrophages) and on other pro-inflammatory cells (including eosinophils and certain myeloid stem cells). CysLTs have been correlated with the pathophysiology of asthma and allergic rhinitis.

Montelukast is an orally active compound that binds with high affinity and selectivity to the CysLT₁ receptor. Montelukast inhibits physiologic actions of LTD₄ at the CysLT₁ receptor without any agonist activity.

INDICATIONS AND USAGE

Ontel is indicated for the prophylaxis and chronic treatment of asthma in adults and pediatric patients 12 months of age and older.

Ontel is indicated for prevention of exercise induced bronchoconstriction in patients 15 years of age and older.

Ontel is indicated for the relief of symptoms of allergic rhinitis (seasonal allergic rhinitis in adults and pediatric patients 2 years of age and older, and perennial allergic rhinitis in adults and pediatric patients 6 months of age and older).

DOSAGE AND ADMINISTRATION

Adults more than 15 years of age

The dosage for adults and adolescents 15 years of age and older is one 10mg tablet to be taken in the evening.

Children 6-14 years of age

The dosage for pediatric patients 6 to 14 years of age is one 5mg tablet to be taken in the evening.

Children 2-5 years of age

The dosage for pediatric patients 2 to 5 years of age is one 4mg chewable tablet to be taken in the evening.

Exercise-Induced Bronchoconstriction (EIB) in Patients 15 years of age and older

For prevention of EIB, a single dose of **Ontel** should be taken at least 2 hours before exercise. An additional dose of **Ontel** should not be taken within 24 hours of a previous dose. Patients already taking one tablet daily for another indication (including chronic asthma) should not take an additional dose to prevent EIB.

Allergic Rhinitis

Seasonal Allergic Rhinitis in Patients 2 years and older

Perennial Allergic Rhinitis in Patients 6 months and older

For allergic rhinitis **Ontel** should be taken once daily. The time of administration may be individualized to suit patient needs.

Safety and effectiveness in pediatric patients younger than 2 years of age with seasonal allergic rhinitis and less than 6 months of age with perennial allergic rhinitis have not been established.

Asthma and Allergic Rhinitis in patients 12 months of age and older

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

PRECAUTIONS

Pregnancy

Pregnancy Category B:

No teratogenicity was observed in rats at oral doses up to 400mg/kg/day (estimated exposure was approximately 100 times the AUC for adults at the maximum recommended daily oral dose) and in rabbits at oral doses up to 300mg/kg/day

(estimated exposure was approximately 110 times the AUC for adults at the maximum recommended daily oral dose). Montelukast crosses the placenta following oral dosing in rats and rabbits. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, montelukast should be used during pregnancy only if clearly needed.

Lactation

It is not known whether montelukast is secreted in human breast milk, therefore caution should be applied while prescribing this drug to nursing mother.

Gender: The pharmacokinetics of montelukast are similar in males and females.

Elderly: The pharmacokinetic profile and the oral bioavailability of a single 10mg oral dose of montelukast are similar in elderly and younger adults. The plasma half-life of montelukast is slightly longer in the elderly. No dosage adjustment in the elderly is required.

Hepatic Insufficiency: Patients with mild-to-moderate hepatic insufficiency and clinical evidence of cirrhosis had evidence of decreased metabolism of montelukast. No dosage adjustment is required in patients with mild-to-moderate hepatic insufficiency.

Renal Insufficiency: Montelukast and its metabolites are not excreted in the urine. No dosage adjustment is recommended in these patients.

Ontel is not indicated for use in the reversal of bronchospasm in acute asthma attacks, including status asthmaticus.

Patients should be advised to have appropriate rescue medication available. Therapy with **Ontel** can be continued during acute exacerbations of asthma. Patients who have exacerbations of asthma after exercise should have available for rescue a short-acting inhaled β -agonist.

CONTRAINDICATIONS

Hypersensitivity to any component of this product.

DRUG INTERACTIONS

Montelukast may be co-administered with other drugs commonly used for the chronic treatment and prophylaxis of asthma. Since the therapeutic dose of montelukast has not

been found to have clinically significant effects on the pharmacokinetics of theophylline, prednisolone, oral contraceptives, terfenadine, digoxin and warfarin, it can safely be co-prescribed with these drugs.

SIDE EFFECTS

Montelukast is generally well tolerated but following side effects may occur: diarrhoea, pharyngitis, laryngitis, nausea, otitis, sinusitis, viral infections, abdominal pain and headache. Side effects are usually mild and do not need therapy withdrawal. The incidence of side effects is comparable to placebo.

OVERDOSAGE

There is no report of overdosage with montelukast in doses as high as 900mg/kg/day. It is not known whether montelukast is dialyzable by peritoneal or hemodialysis.

STORAGE

Store in a cool and dry place. Protect from sunlight. Keep away from the reach of children.

AVAILABILITY

Ontel 4mg Chewable tablets in pack of 14's

Ontel 5mg tablets in pack of 14's

Ontel 10mg tablets in pack of 14's

خوراک اور ہدایت:
ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
دھوپ گرمی اور نمی سے محفوظ رکھیں۔
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

ISO 9001 : 2000 Certified Company

Manufactured by:

Macquin's

MACQUIN'S INTERNATIONAL
F-2/H, P.T.C. Industrial Complex,
S.I.T.E., KARACHI.

Marketed by:

CENRJY
Pharmaceuticals
Karachi