DUNE Tablets

ڈیون ٹیبلٹس

COMPOSITION: *Each tablet contains:* Montelukast (as Sodium)*.....5 & 10 mg respectively.

DESCRIPTION: Montelukast sodium is described chemically as [*R*-(*E*)]-1-[[[1-[3-[2-(7-chloro-2-quinolinyl)ethenyl]phenyl]-3-[2-(1-hydroxy-1- methylethyl) phenyl]propyl]thio] methyl] cyclopropaneacetic acid, monosodium salt. The empirical formula is $C_{35}H_{35}ClNNaO_3S$, and its molecular weight is 608.18.

PHARMACOLOGY: *Pharmacodynamics:* Montelukast sodium is a selective and orally active leukotriene receptor antagonist that inhibits the cysteinyl leukotriene $CysLT_1$ receptor. The cysteinyl leukotrienes (LTC4, LTD4, LTE4) are products of arachidonic acid metabolism and are released from various cells, including mast cells and eosinophils. CysLTs have been correlated with the pathophysiology of asthma and allergic rhinitis. The CysLT type-1 ($CysLT_1$) 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). In asthma, leukotriene-mediated effects include airway edema, smooth muscle contraction, and altered cellular activity associated with the inflammatory process. In allergic rhinitis, CysLTs are released from the nasal mucosa after allergen exposure during both early and late-phase reactions and are associated with symptoms of allergic rhinitis. *Pharmacokinetics:* Montelukast is rapidly absorbed following oral administration. The mean oral bioavailability is 64% with 10 mg tablet and 73% with 5 mg tablet. The oral bioavailability and Cmax are not influenced by a standard meal in the morning. Montelukast is extensively metabolized. *In vitro* studies using human liver microsomes indicate that cytochromes P450 3A4 and 2C9 are involved in the metabolism of montelukast. The plasma clearance of montelukast averages 45 mL/min in healthy adults. The mean plasma half-life of montelukast ranges from 2.7 to 5.5 hours in healthy young adults. Montelukast and its metabolites are excreted almost exclusively via the bile.

INDICATIONS: DUNE Tablets are indicated for the prophylaxis and chronic treatment of asthma. DUNE Tablets are also indicated for the relief of symptoms of seasonal allergic rhinitis.

CONTRAINDICATIONS: Hypersensitivity to any component of the formulation.

POSSIBLE ADVERSE EFFECTS: Montelukast is generally well tolerated. The following adverse reactions have been reported: anaphylaxis, angioedema, pruritus, urticaria, dream abnormalities, hallucinations, drowsiness, irritability, agitation including aggressive behaviour, restlessness, insomnia, paraesthesia/hypoesthesia, nausea, vomiting, dyspepsia, diarrhea, arthralgia, myalgia including muscle cramps, increased bleeding tendency, bruising, palpitations and edema. Hepatic eosinophilic infiltration, seizures, pancreatitis and cholestatic hepatitis occur rarely.

DRUG INTERACTIONS: Phenobarbital, which induces hepatic metabolism, decreased the AUC of montelukast approximately 40% following a single 10 mg dose of montelukast. No dosage adjustment for montelukast is recommended. Appropriate clinical monitoring should be done when potent cytochrome P450 enzyme inducers, such as phenobarbital or rifampin, are co-administered with montelukast. The recommended clinical dose of montelukast did not have clinically important effects on the pharmacokinetics of the following drugs: theophylline, prednisone, prednisolone, oral contraceptives, terfenadine, digoxin, and warfarin. Montelukast has been used concomitantly with a wide range of commonly prescribed drugs in clinical studies without evidence of clinical adverse interactions. These medications included thyroid hormones, sedative hypnotics, non-steroidal anti-inflammatory agents, benzodiazepines, and decongestants.

WARNINGS: *General:* Montelukast 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 montelukast can be continued during acute exacerbations of asthma. While the dose of inhaled corticosteroid may be reduced gradually under medical supervision, montelukast should not be abruptly substituted for inhaled or oral corticosteroids. Montelukast should not be used as monotherapy for the treatment and management of exercise-induced bronchospasm. Patients who have exacerbations of asthma after exercise should continue to use their usual regimen of inhaled ß-agonists as prophylaxis and have available for rescue a short-acting inhaled ß-agonist. 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 non-steroidal anti-inflammatory drugs in aspirin-sensitive asthmatic patients. *Eosinophilic Conditions:* In rare cases, patients with asthma on therapy with montelukast may present with systemic eosinophilia, sometimes presenting with clinical features of vasculitis consistent with Churg-Strauss syndrome, a condition, which is often treated with systemic corticosteroid therapy. *Pregnancy:* Since no adequate and well-controlled studies in pregnant women are available, montelukast should be used during pregnancy only if clearly needed. *Lactation:* It is not known if montelukast is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when montelukast is given to a nursing mother. *Pediatric Patients:* The safety and effectiveness in pediatric patients below the age of 12 months have not been established.

DOSAGE & ADMINISTRATION: DUNE Tablets should be taken once-daily. For asthma, the dose should be taken in the evening. For seasonal allergic rhinitis, the time of administration may be individualized to suit patient needs. Patients with both asthma and seasonal allergic rhinitis should take only 1 tablet daily in the evening. *Adults & Adolescents 15 Years of Age and Older with Asthma or Seasonal Allergic Rhinitis:* The dosage for adults and adolescents 15 years of age and older is 1 tablet of DUNE 10 mg daily. *Pediatric Patients 6 to 14 Years of Age with Asthma or Seasonal Allergic Rhinitis:* The dosage for pediatric patients 6 to 14 years of age is 1 tablet of DUNE 5 mg daily. No dosage adjustment within this age group is necessary.

SPECIAL INSTRUCTIONS TO THE PHYSICIAN: *Overdosage:* No specific information is available on the treatment of overdosage with montelukast. In the event of overdose, it is reasonable to employ the usual supportive measures; e.g., remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring, and institute supportive therapy, if required.

STORAGE/PRECAUTIONS: Store in cool, dry and dark place between 15-30 °C. Keep all medicines out of the children's reach.

PRESENTATION: DUNE 5 & 10 mg Tablets are available in packing containing 14 tablets, respectively. **Scotmann Specs.*

عمومی خوراک: ڈاکٹر کی ہدایت کے مطابق۔

احتیاط: دوا صرف مستند ڈاکٹر کے زیرِ ہدایت استعمال کریں۔ روشنی، نمی اور گرمی سے بچائیں۔ 15 سے 30 ڈگری سینٹی گریڈ کے درمیان محفوظ کریں۔ تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

Complete Medical Information available only for doctors on request.

Manufactured by:
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