TAIR

COMPOSITION:

TAIR 4mg Tablets
Each chewable tablet contains:
Montelukast Sodium 4.16mg equivalent to Montelukast (U.S.P).. .4mg
TAIR 5mg Tablets
Each chewable tablet contains:
Montelukast Sodium 5.2mg equivalent to Montelukast (U.S.P) 5mg
TAIR 10mg Tablets
Each chewable tablet contains:
Montelukast Sodium 10.4mg equivalent to Montelukast (U.S.P).....10mg

DESCRIPTION:

Montelukast Sodium, the active ingredient in TAIR, is a selective and orally active leukotriene receptor antagonist that inhibits the cysteinyl leukotriene CysLT receptor. Montelukast Sodium is described chemically as [R-(E)]-1-[[[1-[3-[2-(7-chloro-2quinolinyl) ethenyl] phenyl]-3-[2-(1-hydroxy-1-methylethyl) phenyl] propyl] thio]methyl]cyclopropaneaceti acid, x 62.74 mm dium salt. The empirical formula is C, HCINNAOS and its molecular weight is 608.18. Monteluk..8716 mm um is a hygroscopic, optically active, white to off white powder. Montelukast Sodium is freely soluble in ethanol, methanol and water and practically insoluble in acetonitrile.

MECHANISM OF ACTION:

Montelukast is an orally active compound that binds with high affinity and selectivity to the CyLT1 receptor (n preference to other pharmacologically Important airway receptors, such as the prostanold, cholinergic, or Badrenergic receptor). Montelukast inhibits physiologic actions of LTD4 at the CysLT1 receptor without any agonist activity.

PHARMACOKINETIC:

Absorption: Montelukast (TAIR) is rapidly absorbed following oral administration, Aher administration of the 10mg chewable tablet to fasted adults, the mean peak Montelukast plasma concentration (Cmax) is achieved in 3 to 4 hours (Tmad. The mean oral bioavailability is 64%. The oral bioavailability and Cmax are not influenced by a standard meal in the morning. For the Montelukast (TAIRO Sing chewable tablet, the mean Cmax is achieved in 2 to 2.5 hours after administration to adults in the fasted state. The mean oral bioavallability is 73% in the fasted state versus 63% when administered with a standard meal in the morning For the Montelukast (TAIR) 4mg chewable tablet, the mean Cmax is achieved 2 hours after administration in pediatric patients 2 to 5 years of age in the fasted state.
Distribution: Montelukast is more than 99% bound to plasma proteins. The steady state volume of debribution of Montelukast averages 8 to 11 ters Studies in rats with radiolabeled Montelukast indicate minimal distribution across the blood brain barrier. In additions, concentrations of radiolabeled material at 24 hours postdose were minimal in all other tissues.
Metabolism: Montelukast is extensively metabolized. In studies with therapeutic doses, plasma concentrations of metabolites undetectable at steady state in adults and pediatric patients Montelukast

are in vitro studies using human liver microsomes indicate that CYP3A4, 208 and 209 are involved in the metabolism of Montelukast. At dinically relevant concentrations, 208 appears to play a major role in the metabolism of Montelukast

Elimination: The plasma clearance of Montelukast averages 45 ml/min in healthy adults. Following an oral dose of radiolabeled Montelukast, 56% of the radioactivity was recovered in 5 day fecal collections and 0.2% was recovered in urine Coupled with estimates of Montelukast oral bioavailability, this indicates that Montelukast and its metabolites are excreted almost exclusively via the bile

Special Populations

Hepatic insufficiency:

Patients with mild to moderate hepatic insufficiency and clinical evidence of cinhosis had evidence of decreased metabolism of Montelukast resulting in 41% higher mean Montelukast AUC following a single 10mg dose. The elimination of Montelukast was slightly prolonged compared with that in healthy subjects (mean half life, 74 hours). No dosage adjustment is required in patients with mild to moderate hepatic insufficien cy. The pharmacokinetics of Montelukast (TAIKO in patients with more severe hepatic impairment or with hepatitis have not been evaluated.

Renal Insufficiency: Since Montelukast and Its metabolites are not excreted in the urine, the pharmacokinetics of Montelukast were not evaluated in patients with renal insufficiency. No dosage adjustment is recommended in these patients.

Gender: The pharmacokinetics of Montelukast are similar in males and females

Adolescents and Pediatric Patients: Pharmacokinetic studies evaluated the systemic exposure of the 4mg chewable tablets in pediatric patients 2 to 5 years of age, the Smg chewable tablets in pediatric patients 6 to 14 years of age and the 10mg chewable tablets in young adults and adolescents 2 15

INDICATIONS:

Tair is indicated for:

Asthma: Montelukast (TAIR) is indicated for the prophylaxis and chronic treatment of asthma in adults and pediatric patients 12 months of age and older.

Exercise Induced Bronchoconstriction (DB): Montelukast (TANO is indicated for prevention of exerche induced bronchoconstriction (E8) in patients 6 years of age and older

Allergic Rhinitis: Montelukast (TAIRQ is indicated for the relief of symptoms of seasonal allergic rhinitis in patients 2 years of age and older and perennial allergic rhinitis in patients 6 months of age and older.

DOSAGE AND ADMINISTRATION:

Asthma: Montelukast (TAIR) should be taken once daily in the evening. The following doses are recommended:

For adults and adolescents 15 years of age and older: 10mg chewable tablet once daily

For pediatric patients 6 to 14 years of age 5mg chewable tablet once daily

For pediatric patients 2 to 5 years of age: 4mg chewable tablet once daily

Exercise Induced Bronchoconstriction (EB): For prevention of ER, a single dose of Montelukast (TAIR)

TAIR

For adults and adolescents 15 years of age and older: 10mg chewable tablet once daily.
For pediatric patients 6 to 14 years of age: 5mg chewable tablet once daily.
Allergic Rhinitis: For allergic rhinitis, Montelukast (TAIR) should be taken once daily. Efficacy was demonstrated for seasonal allergic rhinitis when Montelukast (TAIR) was administered in the morning or the evening without regard to time of food Ingestion. The time of administration may be Individualized to suit patient needs.
The following doses for the treatment of symptoms of seasonal allergic rhinitis are recommended:
For adults and adolescents 15 years of age and older: 10mg chewable tablet once daily.
For pediatric patients 6 to 14 years of age: 5mg chewable tablet once daily.
For pediatric patients 2 to 5 years of age: 4mg chewable tablet once daily.

CONTRAINDICATIONS:

Hypersensitivity to any component of this product.

PRECAUTIONS:

Acute Asthmat: Montelukast (TAIR) is not indicated for use in the reversal of bronchospasm in acute asthena attacks, including status asthmaticus. Patients should be advised to have appropriate rescue medication available. Therapy with Monteldast (TAIRO can be continued during moute acerbations of asthma. Patients who have exacerbations of asthma after exercise should have available for rescue a short acting inhaled -agonist
Concomitant Carticosterald Use: While the dose of inhaled Corticosterold may be reduced gradually under medical supervhion, Mantelukast (TA should not be abruptly substituted for inhaled or oral corticosteroids
Aspirin Sensitivity: Patients with losown Aspirin sensitivity should continue avoidance of Aspirin or Noraheroidal antiinflammatory agents while taking Montelukast (TANG Although Monlekukest (TASR 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 Nonsteroidal and inflammatory drugs in Aspirin sensitive asthmatic patients
Nuropsychlatric Events: Neuropsychietric events have been reported in adult adolescent and pediatric patients taking Montelukast (TAIR) Post marketing reports with Montelukast (TAIR) use include agitation, aggressive behavior or hostility, ardousness, depression, disorientation, disturbance In attention, dream abnormalities halacinations, insomnie, intability, memory impairment, restlessnest, somnambulism, suicidal thinking and behaviorOncluding suicidel, tic and tremor. The clinical details of some post marketing reports involving Mortekukast (TAIR appear consistent with a drug induced effect. Patients and prescribers should be alert for neuropsychiatric events. Patients should be instructed to notify their prescriber if these changes occur. Prescribers should carefully evaluate the risks and benefits of continuing treatment with Montelukast (TARO such events occur.
Eosinophilic Conditions: Pacients with asthma on therapy with Montelukast (TABO may present with systemic eosinophilia, sometimes presenting with dinical features of vasculitis consistent with Churg-Strauss syndrome, & adition which is often treated with syslernic corticosteroid therapy. These events have been sometimes associated with the reduction of oral corticosteroid therapy. Physicians should be alert to ensinophilia, vasculite rash, worsening punanary symptoms, cardiac complications and/or neuropathy presenting in their patients. A causal association between Mantelukas [TARO and these underlying conditions has not been established.

TAIR

PREGNANCY AND LACTATION:

Pregnancy Category : There are no adequate and well controlled studies in pregnant women Because animal reproduction studies are not always predictive of human respome, Montelukast (TARO should be used during pregnancy only if clearly needed LACTATION: Studies in rats have shown that Montelukast is excreted in milk. It is not known Montelukast is excreted in human milik Because many drugs are excreted in human milk caution should be exercised when Monteldast (TARO is given to amuning mother

DRUG-DRUG INTERACTIONS:

No dose adjustment is needed when Montelukast (TAIFO is coad ninistared with Theophyine Prednisolone, Oral contraceptives Terfenadine, Digoxin Warfarin, Gemferozil, leraconazole, Thyroid hormones, Sedalive hypnodos, Nonsteroidal antinflammatory agents, Benzodiazepines, decongestants and Cytochrome P450 (CYP) enzyme Inducer

ADVERSE DRUG REACTIONS:

Adults and Adoleccants: 15 Years of Age and Older with Asthma: Montelukast (TAO has been evaluated for safety in approximately adult andadolescent patients 15 years of age and older in dinical trials. In placebo controlled clinical trials, the following adverse experiences reported withMonlelukast (TAIR) occurred in greater than or equal to 1% of patients and at an incidence greater than that in patients treated with placebo

Body As a Whole: Pain, abdominal, Asthenia/latigue, Fever, Trauma
Digestive Systam Diserders: Dyspepsis, Pain, Dental, Gastroenter
Nervous System/Psychiatric: Headache, Dizziness

Respiratory System Disorders: Influese, Cough, Congestion Pediatric Patients to 14 Years of Age with Asthma: in pediatric patients 6 to 14 years of age receiving Montelukast (TARO, the following events
Skin/skin Appendages Diserder: Rash occurred with a frequency 2 2% and more frequently than in pediatric patients who received placebor pharynghhs, Infuerux, fever, sinun ti, nausea,diarrhea, dyspepsia, odtis, viral infection and laryngitis. The frequency of less common adverse events was comparable between Montkast (TAIR) andplacebo, With prolonged treatment, the adverse experience profile did not significantly change
Pediatric Patients 2 to 5 Years of Age with Asthma: in pediatric patients 2 to 5 years of age receiving Montelukast (TAR, the following events occurredwith a frequency a 2% and more frequendy than in pediatric patients who received placebo leves, cough, abdominal pain, diarrhea, headache,thinorrhea, sinusitis otth, influenza, rash, ear pain, gastroenteritis, eczema, urticart, varicella, pneumonia, dermath and conjunctivitis

OVERDOSE:

No mortality occurred following single oral doses of Montelukast up to 5000 mg/kg in mice (Estimated exposure was approximately 335 and 210 times the AUC for adults and children, respectively, at the maximum recommended daily oral dose) and rats (Estimated exposure was approximately 230 and 145 times the AUC for adults and children, respectively, at the maximum recommended daily oral dose).

Wilshire
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CONTINUE

TAIR

No specific information is available on the treatment of over dosage with Montelukast (TAIR). In chronic asthma studies, Montelukast has been administered at doses up to 200 mg/day to adult patients for 22 weeks and in short term studies, up to 900 mg/day to patients for approximately a week without clinically important adverse experiences. 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.
There have been reports of acute over dosage in post marketing experience and clinical studies with Montelukast (TAIR). These include reports in adults and children with a dose as high as 1000mg. The clinical and laboratory findings observed were consistent with the safety profile in adults and pediatric patients.
There were no adverse experiences in the majority of overdosage reports. The most frequently occurring adverse experiences were consistent with the safety profile of Montelukast (TAIR) and included abdominal pain, somnolence, thirst, headache, vomiting and psychomotor hyperactivity. It is not known whether Montelukast is removed by peritoneal dialysis or hemodialysis.

STORAGE

Store in a cool & dry place below 25°C. Protect from light, heat and moisture. Keep out of reach of children.

PRESENTATION:

TAIR 4mg chewable tablets are available in a blister pack of 30's. TAIR 5mg chewable tablets are available in a blister pack of 20's. TAIR 10mg chewable tablets are available in a blister pack of 20's.