Montexin
(Montelukast)

Chewable Tablets 4 mg
Chewable Tablets 5 mg

[PRODUCT DESCRIPTION]

Montexin Chewable Tablets 4 mg:
It is a pink oval tablet, a ST/025 is scored on one side.
Montexin Chewable Tablets 5 mg:
It is a pink round tablet, a ST/027 is scored on one side.

[INGREDIENTS]

Each Chewable Tablet contains:
Montelukast Sodium 4.2 mg (equivalent to Montelukast 4.0 mg)
Montelukast Sodium 5.2 mg (equivalent to Montelukast 5.0 mg)

[THERAPEUTIC CLASS]

Montelukast Sodium, the active ingredient in Montexin, is a selective and orally active leukotriene receptor antagonist that specifically inhibits the cysteinyl leukotriene CysLT1 receptor.

[INDICATIONS]

Montexin is indicated for the prophylaxis and chronic treatment of asthma in adults and pediatric patients 12 months of age and older.
Montexin is indicated for the relief of symptoms of allergic rhinitis (seasonal allergic rhinitis in adults and pediatric patients 2 years of age and older).

[ROUTE OF ADMINISTRATION] Oral

[DOSAGE AND ADMINISTRATION]

Montexin 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 allergic rhinitis should take only one tablet daily in the evening.

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 one 5-mg chewable tablet daily. No dosage adjustment within this age group is necessary.

Pediatric Patients 2 to 5 Years of Age with Asthma or Seasonal Allergic Rhinitis
The dosage for pediatric patients 2 to 5 years of age is one 4-mg chewable tablet daily.

General Recommendations
The therapeutic effect of Montelukast on parameters of asthma control occurs within one day. Montelukast chewable tablets 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 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.

Therapy with Montelukast in Related to Other Treatments for Asthma
Montelukast can be added to a patient's existing treatment regimen.
Reduction in Concomitant Therapy:
- ***Bronchodilatior 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.

[PHARMACODYNAMICS]

Montelukast causes inhibition of airway cysteinyl leukotriene receptors as demonstrated by the ability to inhibit bronchoconstriction due to inhaled LTD4 in asthmatics. Doses as low as 5 mg cause substantial blockage of LTD4-induced bronchoconstriction. In a placebo-controlled, crossover study (n=12), Montelukast inhibited early- and late-phase bronchoconstriction due to antigen challenge by 75% and 57%, respectively.

The effect of Montelukast on eosinophils in the peripheral blood was examined in clinical trials. In patients with asthma aged 2 years and older who received Montelukast, a decrease in mean peripheral blood eosinophil counts ranging from 9% to 15% was noted, compared with placebo, over the double-blind treatment periods. In patients with seasonal allergic rhinitis aged 15 years and older who received Montelukast, a mean increase of 0.2% in peripheral blood eosinophil counts was noted, compared with a mean increase of 12.5% in placebo-treated patients, over the double-blind treatment periods; this reflects a mean difference of 12.3% in favor of Montelukast. The relationship between these observations and the clinical benefits of Montelukast noted in the clinical trials is not known.

[PHARMACOKINETICS]

Absorption
Montelukast is rapidly absorbed following oral administration.

For the 5-mg chewable tablet, the mean Cmax is achieved in 2 to 2.5 hours after administration to adults in the fasted state. The mean oral bioavailability is 73% in the fasted state versus 63% when administered with a standard meal in the morning.

For the 4-mg 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 distribution of Montelukast averages 8 to 11 liters. Studies in rats with radiolabeled Montelukast indicate minimal distribution across the blood-brain barrier. In addition, 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 of Montelukast are undetectable at steady state in adults and pediatric patients.
In vitro studies using human liver microsomes indicate that cytochromes P450 3A4 and 2C9 are involved in the metabolism of Montelukast. Clinical studies investigating the effect of known inhibitors of cytochromes P450 3A4 (e.g., ketoconazole, erythromycin) or 2C9 (e.g., fluconazole) on Montelukast pharmacokinetics have not been conducted. Based on further in vitro results in human liver microsomes, therapeutic plasma concentrations of Montelukast do not inhibit cytochromes P450 3A4, 2C9, 1A2, 2A6, 2C19, or 2D6. In vitro studies have shown that Montelukast is a potent inhibitor of cytochrome P450 2C8; however, data from a clinical drug-drug interaction study involving Montelukast and rosiglitazone (a probe substrate representative of drugs primarily metabolized by CYP2C8) demonstrated that Montelukast does not inhibit CYP2C8 in vivo, and therefore is not anticipated to alter the metabolism of drugs metabolized by this enzyme.

Elimination
The plasma clearance of Montelukast averages 45 mL/min in healthy adults. Following an oral dose of radiolabeled Montelukast, 86% 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.
In several studies, the mean plasma half-life of Montelukast ranged from 2.7 to 5.5 hours in healthy young adults. The pharmacokinetics of Montelukast are nearly linear for oral doses up to 50 mg.

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

Elderly
The plasma half-life of montelukast is slightly longer in the elderly. No dosage adjustment in the elderly is required.

Race
Pharmacokinetic differences due to race have not been studied.

Hepatic Insufficiency
The elimination of montelukast in patients with mild-to-moderate hepatic insufficiency and clinical evidence of cirrhosis was slightly prolonged compared with that in healthy subjects (mean half-life, 7.4 hours). No dosage adjustment is required in patients with mild-to-moderate hepatic insufficiency. The pharmacokinetics of Montexin 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.

Adolescents and Pediatric Patients
Pharmacokinetic studies evaluated the systemic exposure of the 4-mg chewable tablets in pediatric patients 2 to 5 years of age, and the 5-mg chewable tablets in pediatric patients 6 to 14 years of age.

The mean systemic exposure of the 4-mg chewable tablet in pediatric patients 2 to 5 years of age is similar to the 5-mg chewable tablets in pediatric patients 6 to 14 years of age. The 5-mg chewable tablet should be used in pediatric patients 6 to 14 years of age and the 4-mg chewable tablet should be used in pediatric patients 2 to 5 years of age.

[CONTRAINDICATIONS]

Hypersensitivity to any component of this product.

[WARNING]

Phenylketonuric patients should be informed that the 4-mg and 5-mg chewable tablets contain phenylalanine (a component of aspartame). Therefore, Montexin chewable tablets 4 mg and 5 mg are unsuitable for phenylketonurics.

[PRECAUTIONS]

General
Montexin 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 Montexin can be continued during acute exacerbations of asthma.
While the dose of inhaled corticosteroid may be reduced gradually under medical supervision, Montexin should not be abruptly substituted for inhaled or oral corticosteroids.
Montexin 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 β-agonists as prophylaxis and have available for rescue a short-acting inhaled β-agonist.
Patients with known aspirin sensitivity should continue avoidance of aspirin or non-steroidal anti-inflammatory agents while taking Montexin.
Although Montexin 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 aspirinsensitive asthmatic patients.

Eosinophilic Conditions
In rare cases, patients with asthma on therapy with Montexin 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. These events usually, but not always, have been associated with the reduction of oral corticosteroid therapy. Physicians should be alert to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients. A causal association between Montexin and these underlying conditions has not been established.

Pediatric use
Safety and efficacy of Montelukast have been established in adequate and well-controlled studies in pediatric patients with asthma 6 to 14 years of age. Safety and efficacy profiles in this age group are similar to those seen in adults.

[DRUG INTERACTIONS]

Montexin has been administered with other therapies routinely used in the prophylaxis and chronic treatment of asthma with no apparent increase in adverse reactions. In drug-interaction studies, the recommended clinical dose of Montelukast did not have clinically important effects on the pharmacokinetics of the following drugs: theophylline, prednisone, prednisolone, oral contraceptives (norethindrone 1 mg/ethinyl estradiol 35 mcg), terfenadine, digoxin, and warfarin.
Although additional specific interaction studies were not performed, Montexin was 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.
It is reasonable to employ appropriate clinical monitoring when potent cytochrome P450 enzyme inducers, such as phenobarbital or rifampin, are co-administered with Montexin.

[PREGNANCY AND LACTATION]

Pregnancy
Montelukast has not been studied in pregnant women. Montelukast should be used during pregnancy only if clearly needed.
During worldwide marketing experience, congenital limb defects have been rarely reported in the offspring of women being treated with Montelukast during their pregnancy. Most of these women were also taking other asthma medications during their pregnancy. A causal relationship between these events and Montexin has not been established.

Nursing Mothers
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.

[SIDE EFFECTS]
Montelukast has been generally well tolerated.
Pediatric Patients 6 to 14 Years of Age with Asthma
Pharyngitis, influenza, fever, sinusitis, nausea, diarrhea, dyspepsia, otitis, viral infection, and laryngitis

Pediatric Patients 2 to 5 Years of Age with Asthma
Fever, cough, abdominal pain, diarrhea, headache, rhinorrhea, sinusitis, otitis, influenza, rash, ear pain, gastroenteritis, eczema, urticaria, varicella, pneumonia, dermatitis, and conjunctivitis.

Pediatric Patients 6 to 23 Months of Age with Asthma
Upper respiratory infection, wheezing, otitis media, pharyngitis, tonsillitis, cough, and rhinitis.

Pediatric Patients 2 to 14 Years of Age with Seasonal Allergic Rhinitis
Headache, otitis media, pharyngitis, and upper respiratory infection.

Pediatric Patients 6 Months to 14 Years of Age with Perennial Allergic Rhinitis
The safety in patients 2 to 14 years of age with perennial allergic rhinitis is supported by the established safety in patients 2 to 14 years of age with seasonal allergic rhinitis. The safety in patients 6 to 23 months of age is supported by data from pharmacokinetic and safety and efficacy studies in asthma in this pediatric population and from adult pharmacokinetic studies.

Post-Marketing Experience
The following additional adverse reactions have been reported in post-marketing use: hypersensitivity reactions (including anaphylaxis, angioedema, pruritis, urticaria, and very rarely, hepatic eosinophilic infiltration); dream abnormalities and hallucinations, drowsiness, irritability, agitation including aggressive behavior, restlessness, insomnia, paraesthesia/hypoesthesia, and very rarely seizures; arthralgia, myalgia including muscle cramps; increased bleeding tendency, thrombocytopenia; bruising; palpitations; edema; nausea, vomiting, dyspepsia, diarrhea, and very rarely pancreatitis. Rare cases of cholestatic hepatitis, hepatocellular liver-injury, and mixed-pattern liver injury have been reported in patients treated with Montelukast.

Psychiatric disorders
Obsessive-compulsive symptoms

[OVERDOSAGE]
No specific information is available on the treatment of overdosage with Montelukast. 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 one week without clinically important adverse experiences.
There have been reports of acute overdosage in post-marketing experience and clinical studies with Montelukast. These include reports in adults and children with a dose as high as 1000 mg.
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 and included abdominal pain, somnolence, thirst, headache, vomiting and psychomotor hyperactivity.
It is not known whether Montelukast is dialyzable by peritoneal dialysis or hemodialysis.

[SHELF LIFE]
Montexin Chewable Tablets 4 mg: 2 Years
Montexin Chewable Tablets 5 mg: 2 Years

[STORAGE]
Store below 30°C, and protect from moisture and light.
Keep away from children.

[PACKAGE]

Alu-Alu blister of 7s x 4 pieces per box

REGISTRATION NO.:
Montexin Chewable Tablets 4 mg: MAL 10053672AZ
Montexin Chewable Tablets 5 mg: MAL 10053673AZ

Manufactured by:
TAIWAN BIOTECH CO., LTD.
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Product Registration Holder:
SUNWARD PHARMACEUTICAL SDN. BHD.
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