MONTELUKAST

℞ **BRONAST**

5 mg Chewable Tablet

Leukotriene Receptor Antagonist

FORMULATION:
Each chewable tablet contains:
Montelukast (as sodium) ..... 5 mg

PRODUCT DESCRIPTION:
Triangle shape tablet having monogram on one side.

INDICATIONS:
Used in the management of chronic asthma, allergic rhinitis and as prophylaxis for excercise induced asthma.

DOSAGE & ADMINISTRATION:
Children 6 to 14 years of age one tablet of Bronast 5mg chewable daily at night For SAR : According to Patients needs. For Patients with (Asthma + SAR) : Only one tablet daily in the evening.

CONTRAINDICATIONS:
Bronast is not indicated in case who have shown hypersensitivity to Montelukast Sodium or any of this product and patients with acute asthmatic attack (eg. Asthmaticus).

PRECAUTIONS:
The efficacy of oral Bronast for the treatment of acute asthma attacks has not been established . Therefore , oral tablets of Bronast should not be used to treat acute asthma attacks . Patients should be advised to have appropriate rescue medication available . Bronast should not be abruptly substituted for inhaled or oral corticosteroids .

ADVERSE DRUG REACTION:
Bronast has been generally well tolerated . Side effects are usually mild generally do not require discontinuation of therapy . The overall incidence of side effects reported with Montelukast is comparable of placebo. Some of the common side effects include asthenia , dyspepsia , dizziness , headache, nasal congestion, cough and flu like symptoms in children observed side effects include diarrhea , laryngitis , pharyngitis , nausea etc.

REPORTING OF SUSPECTED ADVERSE REACTION:
To allow continued monitoring of the benefit/risk balance of the medicinal product, reporting of suspected adverse reaction is necessary. Healthcare professionals are encouraged to report any suspected adverse reactions directly to the importer/distributor and/or report to FDA: www.fda.gov.ph. Patients are advised to seek immediate medical attention at first sign/s of adverse reactions.

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 Sodium inhibited early- and late-phase bronchoconstriction due to antigen challenge by 75% and 57%, respectively. The effect of Montelukast Sodium on eosinophils in the peripheral blood was examined in clinical trials. In patients with asthma aged 2 years and older who received Montelukast Sodium, 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 Sodium, 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 Sodium. The relationship between these observations and the clinical benefits of montelukast noted in the clinical trials is not known.

PHARMACOKINETICS:
Montelukast is rapidly absorbed following oral administration. After administration of the 10-mg filmcoated tablet to fasted adults, the mean peak montelukast plasma concentration (Cmax) is achieved in 3 to 4 hours (Tmax).

The mean oral bioavailability is 64%. The oral bioavailability and Cmax are not influenced by a standard meal in the morning. 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. The safety and efficacy of Montelukast Sodium in patients with asthma were demonstrated in clinical trials in which the 10-mg film-coated tablet and 5-mg chewable tablet formulations were administered in the evening without regard to the time of food ingestion. The safety of Montelukast Sodium in patients with asthma was also demonstrated in clinical trials in which the 5mg chewable tablet. The safety and efficacy of Montelukast Sodium in patients with seasonal allergic rhinitis were demonstrated in clinical trials in which the 10-mg film-coated tablet was administered in the morning or evening without regard to the time of food ingestion. The comparative pharmacokinetics of montelukast when administered as two 5-mg chewable tablets versus one 10-mg film-coated tablet has not been evaluated.

INTERACTIONS:
Montelukast Sodium 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, Montelukast Sodium 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. 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 Sodium is recommended. It is reasonable to employ appropriate clinical monitoring when potent cytochrome P450 enzyme inducers, such as phenobarbital or rifampin, are co-administered with Montelukast Sodium.

OVERDOSE & TREATMENT:
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 overdosage in pediatric patients in post-marketing experience and clinical studies of up to at least 150 mg/day with Montelukast Sodium. The clinical and laboratory findings observed were consistent with the safety profile in adults and older pediatric patients. There were no adverse experiences reported in the majority of overdosage reports. The most frequent adverse experiences observed were thirst, somnolence, mydriasis, hyperkinesia, and abdominal pain. It is not known whether montelukast is removed by peritoneal dialysis or hemodialysis.

STORAGE:
Store at temperatures not exceeding 30°C. Protect from light & heat.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.
Keep out of the reach of children.

AVAILABILITY:
Alu/Pvc Blister Pack x 7's (Box of 14's)

FDA Registration Number: DR-XY38938
Date of Renewal of Authorization: 26 March 2021
Date of Revision of Package Insert: 31 March 2021

Manufactured by:
GEOFMAN PHARMACEUTICALS
20/23, Korangi Industrial Area, Karachi, Pakistan.

Imported & Distributed by:
SAHAR INTERNATIONAL TRADING INC.
354 Aguirre Ave., Phase-III, BF Homes, Parañaque City.