PROAIR
Montelukast USP

Composition :
Proair-10 : Each film coated tablet contains Montelukast sodium USP equivalent to Montelukast 10 mg

Proair -5 : Each OD tablet contains Montelukast sodium USP equivalent to Montelukast 5 mg

Pharmacology
Montelukast is a selective and orally active leukotriene receptor antagonist that inhibits the cysteinyl leukotriene receptor($CysLT_1$). The cysteinyl leukotrienes receptor (LTC_4, LTD_4, LTE_4) are products of arachidonic acid metabolism and are released from various cells, including mast cell and eosinophils. Cysteinyl leukotriene and leukotriene receptor occupation have been correlated with the pathophysiology of asthma, including airway edema, smooth muscle contraction, and altered cellular activity associated with the inflammatory process, which contribute to the signs and symptoms of asthma.

Indication:
Proair is indicated for:
• Prophylaxix and chronic treatment of asthma.
• Acute prevention of Exercise-Induced Bronchoconstriction (EIB)
• Relief of symptoms of Allergic Rhinitis (AR): Seasonal and Perennial Allergic Rhinitis.

Dose and administration:

Patients	Asthma & Allergic Rhinitis	Exercise-Induced Bronchoconstriction
Adult and adolescent (15 years and older)	10 mg /day	10 mg /day
Paediatric patients (6 year to 14 years)	5 mg /day	5 mg /day
Paediatric patient (6 month to 5 years)	4 mg /day	Not recommended

Patients with both asthma and allergic rhinitis should take only one dose daily in the evening. For prevention of EIB, a single dose should be taken at least 2 hours before exercise.
Route of administration: Oral Proair (Montelukas) may be taken with or without food or as directed by the physician.

Contraindication:
Montelukast is contraindicated in patients who are hypersensitive to any component of this product.

Warning and precaution:
Montelukast is not indicated for use in the reversal of bronchospasm in acute asthma attacks, including status asthmaticus. Neuropsychiatric events including agitation, hostility, anxiousness, depression, disorientation, disturbance in attention, dream abnormalities, hallucinations, insomnia, irritability, memory impairment, restlessness, somnambulism, suicidal thinking and behavior (including suicide) and tremor.

Side effects:
Common : Montelukast has been generally well tolerated, side effect which usually are mild, including the gastro-intestinal disturbances, dry mouth, thirst, hypersensitivity reaction including anaphylaxis, angioedema and skin reactions; asthenia, dizziness, irritability, restlessness, headache, sleep disorders (insomnia, drowsiness, nightmares); upper respiratory tract infection, fever, arthralgia, myalgia. The overall incidence of side effects reported with montelukast was comparable to placebo.

Rare: Adult and Adolescents : Abdominal pain, asthenia/fatigue, fever, trauma, dyspepsia, dental pain, gastroenteritis, headache, dizziness, influenza, caugh, nasal congestion, rash, pyuria, Pediatric patients: Nausia, diarrhea, dyspepsia, fever, headache, cough, Abdominal pain, rhinorrhea, rash, ear pain, eczema, urticaria, atopic dermatitis, acute bronchitis, tooth infection, skin infection, myopia, pneumonia, conjunctivitis, upper respiratory infection, wheezing, tonsillitis, pharyngitis, influenza, sinusitis, otitis media, viral infection, laryngitis, rhinitis, varicella, gastroenteritis.

Using pregnancy and lactation:
There are no adequate and well-controlled studies in pregnant women. Montelukast should be used during pregnancy only if clearly needed. Montelukast is excreted in milk. So caution should be exercised when Montelukast is given to a nursing mother.

Using children and adolescent:
See dose and administration.

Drug interactions:
With medicine: No dose adjustment is needed when montelukast is co-administered with theophylline, prednisone, prednisolone, terfenadine, digoxin, warfarin, gemfibrozil, itraconazole, thyroid hormones, sedative hypnotics, NSAID, benzodiazepines, decongestants, oral contraceptives, and Cytochrome P450 (CYP) enzyme inducers.

With food and others: Bioavailability and other condition were not significantly observed with food and other conditions.

Overdose:
No specific information is available on the treatment of over dosage. In adults and children dose may be given as highest as 1000 mg.

Storage:
Store in cool, and dry place below $30^{o}C$. Protect from light and moisture. Keep out of reach of children.

Packing:
Proair -10 : Each box contains 2 x 10 film coated tablets in Alu-Alu blister pack.
Proair -5 : Each box contains 2 x 10 orally dispersible tablets in Alu-Alu blister pack

Arges Life
SCIENCE

Manufactured by:
Arges Life Science Limited
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Chattogram, Bangladesh.