Montril-10
Country: **Philippines**
Date: 20-01-2021

140mm

260mm

MONTELUKAST

Montril-10
℞
10 mg Film-Coated Tablet
Leukotriene-Receptor Antagonist

FORMULATION:
Each film-coated tablet contains:
Montelukast, USP .....10 mg.
(as Sodium)

PRODUCT DESCRIPTION:
Montelukast (Montril-10) is a light orange color, circular and biconvex film-coated tablet, having no identification mark.

PHARMACOLOGY:
Pharmacotherapeutic group: Leukotriene receptor antagonist
ATC code: R03D C03

PHARMACODYNAMICS: The cysteinyl leukotrienes (LTC4, LTD4, LTE4) are potent inflammatory eicosanoids released from various cells including mast cells and eosinophils. These important pro-asthmatic mediators bind to cysteinyl leukotriene (CysLT) receptors. The CysLT type-1 (oysLT1) receptor is found in the human ainNay (including ainivay smooth muscle cells and ainNay macrophages) and on other pro-inflammatory cells (including eosinophils and certain myeloid stem cells). CysLTs have been correlated with the pathophysiology of asthma and allergic rhinitis. In asthma, leukotriene-mediated effects include bronchoconstriction, mucous secretion, vascular permeability, and eosinophil recruitment. 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. Intranasal challenge with CysLTs has been shown to increase nasal ainivay resistance and symptoms of nasal obstruction.
Montelukast is an orally active compound which binds with high affinity and selectivity to the CysLT1 receptor.

PHARMACOKINETICS: Absorption: Montelukast is rapidly absorbed following oral administration. For the 10 mg film-coated tablet, the mean peak plasma concentration (Cmax) is achieved 3 hours (Tmax) after administration in adults in the fasted state. The mean oral bioavailability is 64%. The oral bioavailability and Cmax are not influenced by a standard meal. Safety and efficacy were demonstrated in clinical trials where the 10 mg film-coated tablet was administered withoutregard to the timing of food ingestion.

Distribution: Montelukast is more than 99% bound to plasma proteins. The steady-state volume of distribution of montelukast averages 8-11 liters.

Biotransformation: Montelukast is extensively mtabolised. In studies with therapeutic doses, plasma concentrations of metabolites of montelukast are undetectable at steady state in adults and children. In vitro studies using human liver microsomes indicate that cytochrome P450 3A4, 2A6 and 2C9 are involved in the metabolism of montelukast. 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. The contribution of metabolites to the therapeutic effect of montelukast is minimal.

Elimination: The plasma clearance of montelukast averages 45 ml/min in healthy adults. Following an oral dose of radiolabelled montelukast, 86% of the radioactivity was recovered in 5-day faecal 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.

INDICATIONS:
It is used in the management of chronic asthma, allergic rhinitis & seasonal allergic rhinitis as prophylaxis for exercise-induced asthma.

DRUG INTERACTIONS:
Because of the potential for interactions, monitoring is recommended during concurrent use with potent cytochrome P-450 enzyme inducers such as rifampin. Concurrent use with phenobarbital has been shown to reduce AUC for montelukast however, no overdose adjustment is considered necessary.

CONTRAINDICATIONS:
Hypersensitivity to the active substance or to any of the excipients

REPORTING OF SUSPECTED ADVERSE REACTIONS:
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 the first sign/s of adverse reactions.

ADVERSE EFFECTS:
Generally montelukast is well-tolerated. Adverse effects include dizziness, headache, diarrhoea, restlessness, abdominal pain, cough, fever, asthenia, rash and upper respiratory tract infection.

PRECAUTIONS:
Patients are instructed to have appropriate rescue treatment available while on montelukast. When being given concurrently with systematic corticosteroids, appropriate tapering of cortecosteroids is needed under medical supervision. Rarely, reduction of systemic corticosteroid while on another, leukotriene receptor antagonist has been reported to manifest with eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy sometimes presenting as Churg-Strauss syndrome, Caution and appropriate clinical monitoring is recommended when systemic corticosteroid dose reduction is considered in patients on montelukast.

DOSAGE AND ADMINISTRATION:
The recommended dose for adults and adolescents 15 years of age and older with asthma, or with asthma and concomitant seasonal allergic rhinitis, is one 10 mg tablet daily to be taken in the evening.

GENERAL RECOMMENDATIONS: The therapeutic effect of Montelukast 10 mg film-coated tablets on parameters of asthma control occurs within one day. Montelukast 10 mg film-coated tablets may be taken with or without food. Patients should be advised to continue taking Montelukast 10 mg film-coated tablets even if their asthma is under control, as well as during periods of worsening asthma. Montelukast 10 mg film-coated tablets should not be used concomitantly with other products containing the same active ingredient, montelukast.

No dosage adjustment is necessary for the elderly, or for patients with renal insufficiency, or mild to moderate hepatic impairment. There are no data on patients with severe hepatic impairment. The dosage is the same for both male and female patients.

THERAPY WITH MONTELUKAST 10 MG FILM-COATED TABLETS IN RELATION TO OTHER TREATMENTS FOR ASTHMA: Montelukast 10 mg film-coated tablets can be added to a patient's existing treatment regimen.

INHALED CORTICOSTEROIDS: Treatment with Montelukast 10 mg film-coated tablets can be used as add-on therapy in patients when inhaled corticosteroids plus "as needed" short acting β-agonists provide inadequate clinical control. Montelukast 10 mg film-coated tablets should not be abruptly substituted for inhaled corticosteroids.

PAEDIATRIC POPULATION: Do not give Montelukast 10 mg film-coated tablets to children less than 15 years of age. The safety and efficacy of Montelukast 10 mg film-coated tablets in children less than 15 years has not been established.

PREGNANCT & LACTATION:
PREGNANCY: Animal studies do not indicate harmful effects with respect to effects on pregnancy or embryonal/foetal development.
Available data from published prospective and retrospective cohort studies with montelukast use in pregnant women evaluating major birth defects have not established a drug-associated risk. Available studies have methodologic limitations, including small sample size, in some cases retrospective data collection, and inconsistent comparator groups.
Montelukast 10 mg film-coated tablets may be used during pregnancy only if it is considered to be clearly essential.

BREASTFEEDING: It is unknown whether montelukast is excreted in human milk. Studies in rats have shown that montelukast is excreted in milk. Montelukast 10 mg film-coated tablets may be used in breast-feeding only if it is considered to be clearly essential.

OVERDOSE AND TREATMENT:
The most frequently occurring adverse effects are abdominal pain, somnolence, thirst, headache, vomiting, and psychomotor hyperactivity.
No specific information is available on the treatment of overdose with montelukast. It is not known whether montelukast is dialysable by peritoneal- or hemodialysis.

CAUTION:
Foods, Drugs, Devices & Cosmetics Act prohibits dispensing without prescription.

STORAGE:
Store at temperature not exceeding 30°C.

AVAILABILITY:
Alu/Alu blister pack 10's (Box of 20's).

FDA Registration No. : DR-XY44285
Date of Renewal of Authorization : 20 January 2020
Date of Revision of package insert : 02 January 2021

20002331/05

Manufactured by :
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