MONTA 5
Montelukast Tablets 5 mg

COMPOSITION:
Each film coated tablet contains:
Montelukast Sodium BP
Eq. to Montelukast 5 mg
Excipients q.s.
Colour: Ferric Oxide of Red USP

DESCRIPTION:
Monta 5 contains Montelukast Sodium 5 mg. Montelukast Sodium is indicated for the treatment of asthma.

PHARMACODYNAMICS:
Pharmacotherapeutic group: Other systemic drugs for obstructive airway diseases, Leukotriene receptor antagonist
ATC code: R03D C03
Montelukast is an orally active compound which binds with high affinity and selectivity to the CysLT1 receptor. In clinical studies, montelukast inhibits bronchoconstriction due to inhaled LTD4 at doses as low as 5 mg. Bronchodilation was observed within 2 hours of oral administration. The bronchodilation effect caused by a beta agonist was additive to that caused by montelukast. Treatment with montelukast inhibited both early- and late phase bronchoconstriction due to antigen challenge. Montelukast, compared with placebo, decreased peripheral blood eosinophils in adult and paediatric patients. In a separate study, treatment with montelukast significantly decreased eosinophils in the airways (as measured in sputum) and in peripheral blood while improving clinical asthma control.

PHARMACOKINETICS:
Absorption
Montelukast is rapidly absorbed following oral administration. For the Montelukast Tablets 5 mg, 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 Montelukast Tablets was administered without regard to the timing of food ingestion.
For the 5 mg chewable tablet, the Cmax is achieved in 2 hours after administration in adults in the fasted state. The mean oral bioavailability is 73% and is decreased to 63% by a standard meal.
Distribution
Montelukast is more than 99% bound to plasma proteins. The steady-state volume of distribution of montelukast averages 8-11 litres. Studies in rats with radiolabelled montelukast indicate minimal distribution across the blood-brain barrier. In addition, concentrations of radiolabelled material at 24 hours post-dose were minimal in all other tissues.
Biotransformation
Montelukast is extensively metabolised. In studies with therapeutic doses, plasma concentrations of metabolites of montelukast are undetectable at steady state in adults and children.
Cytochrome P450 2C8 is the major enzyme in the metabolism of montelukast. Additionally CYP 3A4 and 2C9 may have a minor contribution, although itraconazole, an inhibitor of CYP 3A4, was shown not to change pharmacokinetic variables of montelukast in healthy subjects that received 10 mg montelukast daily. Based on 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.
Characteristics in patients
No dosage adjustment is necessary for the elderly or mild to moderate hepatic insufficiency. Studies in patients with renal impairment have not been undertaken. Because montelukast and its metabolites are eliminated by the biliary route, no dose adjustment is anticipated to be necessary in patients with renal impairment. There are no data on the pharmacokinetics of montelukast in patients with severe hepatic insufficiency (Child-Pugh score>9).
With high doses of montelukast (20- and 60-fold the recommended adult dose), decrease in plasma theophylline concentration was observed. This effect was not seen at the recommended dose of 10 mg once daily.

INDICATION:
Montelukast Tablets is indicated in the treatment of asthma as add-on therapy in adults and adolescents from 15 years of age and older with mild to moderate persistent asthma who are inadequately controlled on inhaled corticosteroids and in whom "as-needed" short acting beta-agonists provide inadequate clinical control of asthma. In those asthmatic patients in whom Montelukast tablets indicated in asthma, Montelukast tablets can also provide symptomatic relief of seasonal allergic rhinitis.
Montelukast is also indicated in the prophylaxis of asthma in which the predominant component is exercise-induced bronchoconstriction.

DOSAGE AND ADMINISTRATION:
Method of administration:
For oral use.
Posology:
The dosage for children and adolescents 6-14 years of age is one 5 mg tablet daily to be taken in the evening.
Montelukast sodium should not be used concomitantly with other products containing the same active ingredient, montelukast.

CONTRAINDICATION:
Monta is contraindicated in patients with:
- Hypersensitivity to the active substance, or any of the excipients.

SPECIAL WARNING AND PRECAUTION FOR USE:
Patients should be advised never to use oral montelukast to treat acute asthma attacks and to keep their usual appropriate rescue medication for this purpose readily available. If an acute attack occurs, a short-acting inhaled beta-agonist should be used. Patients should seek their doctor's advice as soon as possible if they need more inhalations of short-acting beta-agonists than usual.
Montelukast should not be substituted abruptly for inhaled or oral corticosteroids.
There are no data demonstrating that oral corticosteroids can be reduced when montelukast is given concomitantly.
In rare cases, patients on therapy with anti-asthma agents including montelukast 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 cases usually, but not always, have been associated with the reduction or withdrawal of oral corticosteroid therapy. The possibility that leukotriene receptor antagonists may be associated with emergence of Churg-Strauss syndrome can neither be excluded nor established. Physicians should be alert to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients. Patients who develop these symptoms should be reassessed and their treatment regimens evaluated.
Treatment with montelukast does not alter the need for patients with aspirin-sensitive asthma to avoid taking aspirin and other non-steroidal anti-inflammatory drugs.
This medicinal product contains lactose monohydrate.
Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

INTERACTION WITH OTHER MEDICINE AND CONCOMITANT USE:
The area under the plasma concentration curve (AUC) for montelukast was decreased approximately 40% in subjects with co-administration of phenobarbital. Since montelukast is metabolised by CYP 3A4, 2C8, and 2C9, caution should be exercised, particularly in children, when montelukast is co-administered with inducers of CYP 3A4, 2C8, and 2C9, such as phenytoin, phenobarbital and rifampicin.
montelukast and rosiglitazone (a probe substrate representative of medicinal products primarily metabolized by CYP 2C8) demonstrated that montelukast does not inhibit CYP 2C8 in vivo. Therefore, montelukast is not anticipated to markedly alter the metabolism of medicinal products metabolised by this enzyme (e.g., paclitaxel, rosiglitazone, and repaglinide.)
In vitro studies have shown that montelukast is a substrate of CYP 2C8, and to a less significant extent, of 2C9, and 3A4. I

PREGNACY AND LACTATION:
Pregnancy
Animal studies do not indicate harmful effects with respect to effects on pregnancy or embryonal/foetal development.
Limited data from available pregnancy databases do not suggest a causal relationship between Montelukast tablets and malformations (i.e. limb defects) that have been rarely reported in worldwide post marketing experience.
Montelukast tablets may be used during pregnancy only if it is considered to be clearly essential.
Lactation
It is unknown whether montelukast is excreted in human milk. Studies in rats have shown that montelukast is excreted in milk.
Montelukast tablets may be used in breast-feeding only if it is considered to be clearly essential.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:
Montelukast is not expected to affect a patient's ability to drive a car or operate machinery. However, in very rare cases, individuals have reported drowsiness or dizziness.

UNDESIRABLE EFFECTS:
The frequency using the following convention: Common (≥1/100 to <1/10); Uncommon (≥ 1/1,000 to <1/100); Uncommon (≥1/1,000 to <1/100); Rare (≥1/10,000 to <1/1,000); Very rare (<1/10,000); not known (cannot be estimated from the available data).
Infections and infestations
Very Common - upper respiratory infection
Blood and lymphatic system disorders
Rare - increased bleeding tendency
Immune system disorder
Uncommon - hypersensitivity reactions including anaphylaxis
Very Rare - hepatic eosinophilic infiltration
Psychiatric disorders
Uncommon - dream abnormalities including nightmares, insomnia, somnambulism, irritability, anxiety, restlessness, agitation including aggressive behaviour or hostility, depression, psychomotor hyperactivity (including irritability, restlessness, tremor
Rare - disturbance in attention, memory impairment
Very Rare - hallucinations, disorientation, suicidal thinking and behaviour (suicidality)
Nervous system disorder
Uncommon - dizziness, drowsiness paraesthesia/hypoesthesia, seizure
Cardiac disorders
Rare – palpitations
Respiratory, thoracic and mediastinal disorders
Uncommon – epistaxis
Gastrointestinal disorders
Common - diarrhoea, nausea, vomiting
Uncommon - dry mouth, dyspepsia
Skin and subcutaneous tissue disorders
Common - rash
Uncommon - bruising, urticaria, pruritus
Rare - angiooedema

OVERDOSE:
Symptoms
No specific information is available on the treatment of overdose with montelukast. In chronic asthma studies, montelukast has been administered at doses up to 200 mg/day to 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 overdose in post-marketing experience and clinical studies with montelukast. These include reports in adults and children with a dose as high as 1000 mg (approximately 61 mg/kg in a 42 month old child). The clinical and laboratory findings observed were consistent with the safety profile in adults and paediatric patients. There were no adverse experiences in the majority of overdose 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
Treatment
It is not known whether montelukast is dialysable by peritoneal- or haemo-dialy.

INCOMPATIBILITY:
Not applicable.

SHELF LIFE:
3 years

PACKAGING:
10 tablets are packed in Alu- Alu Blister and such 1 blister is packed in a printed carton along with pack insert.

STORAGE CONDITION:
Store in a dry place below 30°C. Protect from light and moisture.
Keep out of reach of children.

MANUFACTURED BY:
CIAN HEALTH CARE PVT. LTD.,
Khasra No.: 248, Sisona, Bhagwanpur,
Roorkee, Haridwar, Uttarakhand, India.

Insert

Prepared By :
Checked By :
Approved By :

Montelukast Tablets	
Monta 5	
Product Item Code & Date	CRPE5156 - 03-10-2015
INSERT SIZE-L x H (MM)	105 x 297 mm (Front Back)
TYPE OF INSERT	50 gsm, Maplitho Paper Front Back with Folding
MFG. LOCATION	Cian Roorkee
COLOUR SCHEME	1 Colour
COUNTRY NAME	Kenya

R-No.	R-Date	REMARK
R-1	03-10-2015	Item code added
R-2	00-00-2015	
R-3	00-00-2015	