SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF DRUG PRODUCT

Montiget Tablets 10mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:
Montelukast Sodium equivalent to Montelukast…...10mg

3. PHARMACEUTICAL FORM

Cream to light yellow colored square shaped film coated tablet having bisected line on one side and plain on other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

MONTIGET (Montelukast sodium) is indicated in adult and pediatric patients 6 months of age and older for the prophylaxis and chronic treatment of asthma including:

- The prevention of day and night time symptoms.
- The treatment of aspirin-sensitive asthmatic patients.
- The prevention of exercise-induced bronchoconstriction.

MONTIGET (Montelukast sodium) is also indicated in adults and pediatric patients 2 years of age and older for the relief of symptoms of seasonal allergic rhinitis.

4.2 Posology and Method of Administration

The therapeutic effect of montelukast sodium on parameters of asthma control occurs within one day. MONTIGET (Montelukast sodium) tablets, and pediatric granules can be taken with or without food. Patients should be advised to continue taking the drug while their asthma is controlled as well as during periods of worsened asthma.

MONTIGET (Montelukast sodium) 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 seasonal allergic rhinitis should take only one tablet or sachet daily in the evening.

Adults and Adolescents 15 Years of Age and Older with Asthma or Seasonal Allergic Rhinitis:
The dosage for adults and adolescents 15 years of age and older is one 10mg tablet daily.

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 5mg chewable tablet daily.

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 4mg chewable tablet or one sachet of pediatric granules 4mg daily.

Pediatric Patients 6 Months to 2 years of Age with Asthma:
The dosage for pediatric patients 6 months to 2 years of age is one sachet of pediatric granules 4mg daily to be taken in the evening.

Use of MONTIGET (Montelukast sodium) in relation to other treatment for asthma
MONTIGET (Montelukast sodium) can be added to a patient's existing treatment regimen.

Reduction in concomitant therapy
Bronchodilator Treatment: MONTIGET (Montelukast sodium) can be added to the treatment 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 MONTIGET (Montelukast sodium) 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 the inhaled corticosteroids can be tapered off completely. MONTIGET (Montelukast sodium) should not be abruptly substituted for inhaled corticosteroids

4.3 Contraindications:

Montelukast sodium is contraindicated in a patient who has shown hypersensitivity to the drug or any of its components. Montelukast sodium is not indicated for use in acute asthma attacks including status asthmaticus.

4.4 Special warnings and special precautions for use

- Montelukast sodium should not be abruptly substituted for inhaled or oral corticosteroids. However, the dose of inhaled corticosteroid may be reduced gradually under medical supervision.
- Although a causal relationship with leukotriene receptor antagonism has not been established, caution and appropriate clinical monitoring is recommended when systemic corticosteroid reduction is considered in patients receiving montelukast sodium.
- Montelukast sodium should not be used as monotherapy for the treatment and management of exercise-induced asthma. Patients who have exacerbations of asthma after exercise should continue to use their usual regimen of inhaled β-agonists as prophylaxis and should have it available as and when required.
- Montelukast sodium does not block bronchoconstrictor response to aspirin or non-steroidal anti-inflammatory drugs in aspirin-sensitive asthmatic patients. Such patients should continue to avoid aspirin and other non-steroidal anti-inflammatory drugs.
- Caution should be exercised when using montelukast sodium with bronchodilator therapy. When clinical response is apparent the bronchodilator therapy should be reduced.

4.5 Interaction with other medicaments

It is recommended that clinical monitoring, particularly in children, be conducted when potent hepatic enzyme inducers such as phenytoin, phenobarbital, or rifampicin are given with montelukast sodium. No dosage adjustment for MONTIGET (Montelukast sodium) is recommended.

4.6 Fertility, pregnancy and lactation

Pregnancy
Montelukast sodium has not been studied in pregnant women. It should be used during pregnancy only if clearly needed.
Nursing Mothers
It is not known if montelukast sodium is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when MONTIGET is given to a nursing mother.

4.7 Effects on ability to drive and operate machines

Montelukast has no or negligible influence on the ability to drive and use machines. However, individuals have reported drowsiness and dizziness.

4.8 Undesirable effects

Common or very common:
Diarrhea, fever, gastrointestinal discomfort, headache, nausea, skin reactions, upper respiratory tract infection and vomiting.

Uncommon:
Akathisia, anxiety, arthralgia, asthenia, behavior abnormal, depression, dizziness, drowsiness, dry mouth, haemorrhage, irritability, malaise, muscle complaints, oedema, seizure, sensation abnormal and sleep disorders.

Rare or very rare:
Angioedema, concentration impaired, disorientation, eosinophilic granulomatosis with polyangiitis, erythema nodosum, hallucination, hepatic disorders, memory loss, palpitations, pulmonary eosinophilia, suicidal tendencies and tremor.
Eosinophilic granulomatosis with polyangiitis (Churg-Strauss syndrome) has occurred very rarely in association with the use of montelukast; in many of the reported cases the reaction followed the reduction or withdrawal of oral corticosteroid therapy.

4.9 Overdosage

No specific information is available on the treatment of overdosage with Montelukast.
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.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Leukotriene receptor antagonists
ATC Code: R03DC03

5.1 Pharmacodynamic properties

Mechanism of Action:
MONTIGET (Montelukast sodium) is a competitive, selective and orally active leukotriene D4 (cysteinyl leukotriene CysLT1) receptor antagonist. The cysteinyl leukotrienes (LTC4, LTD4, LTE4) are products of arachidonic acid metabolism and are released from various cells, including mast cells and eosinophils. These eicosanoids bind to cysteinyl leukotriene (CysLT) receptors. Binding of cysteinyl leukotrienes to leukotriene receptors has been correlated with the pathophysiology of asthma, including airway edema, smooth muscle contraction, and altered cellular activity associated with the inflammatory process, factors that contribute to the signs and symptoms of asthma. Thus, montelukast sodium inhibits physiologic actions of LTD4 at the CysLT1 receptors, without any agonist activity.

5.2 Pharmacokinetic Properties

Absorption:
Montelukast sodium is rapidly absorbed following oral administration. Peak plasma concentrations of montelukast sodium are achieved in 2 to 4 hours after oral administration. The mean oral bioavailability is 64%.

Distribution:
Montelukast sodium is more than 99% bound to plasma proteins. The mean plasma half-life of montelukast sodium ranged from 2.7 to 5.5 hours in healthy young adults. The pharmacokinetics of montelukast sodium is nearly linear for oral doses up to 50mg.

Metabolism:
Montelukast sodium is extensively metabolized in the liver by cytochrome P450 isoenzymes CYP3A4, CYP2A6 and CYP2C9. Therapeutic plasma concentrations of montelukast sodium do not inhibit cytochromes P450 3A4, 2C9, 1A2, 2A6, 2C19, or 2D6.

Elimination:
The plasma clearance of montelukast sodium averages 45mL/min in healthy adults. Montelukast sodium and its metabolites are excreted principally in the feces via the bile.

Special Populations:
Elderly, pediatric, males, females, and patients with renal insufficiency have similar plasma pharmacokinetic profiles as young adults.

Hepatic Insufficiency:
Patients with mild-to-moderate hepatic insufficiency and clinical evidence of cirrhosis has evidence of decreased metabolism and prolonged elimination half-life of montelukast sodium resulting in 41% higher mean montelukast sodium area under the plasma concentration curve (AUC) following a single 10mg dose. No dosage adjustment is required in patients with mild-to-moderate hepatic insufficiency.

Pediatric Patients:
In children 6 to 11 months of age, the systemic exposure to montelukast and the variability of plasma montelukast concentrations were higher than those observed in adults. Safety and tolerability of montelukast in a single dose pharmacokinetic study in children 6 to 23 months of age were similar to that of patients two years and above.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline Cellulose (Avicel PH-102), Lactose Monohydrate, Hydroxypropyl Cellulose (Klucel LF PHARM), Croscarmellose Sodium, Magnesium Stearate and Opadry II yellow 85G32558.

6.2 Incompatibilities

None

6.3 Shelf-life

3 Years

The expiration dates refer to the product correctly stored in the required conditions.

6.4 Special precautions for storage

Store below 30°C.

Protect from sunlight & moisture.

The expiration date refers to the product correctly stored at the required conditions.

6.5 Nature and contents of container

Montiget Tablets 10mg are available in Alu - Alu blister pack of 4 x 7's (28's) in a unit carton along with the package insert.

6.6 Instructions for use/handling

To be sold on prescription of a registered medical practitioner only.

Keep out of the reach of children.

7. MARKETING AUTHORISATION HOLDER

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8. PRODUCT REGISTRATION NUMBER

034838
007199-EX

9. DATE OF PRODUCT REGISTRATION ISSUED

Dec 20, 2004
June 29, 2018