LUK ST®

Montelukast Sodium

Pharmacological properties

Lukast® (Montelukast sodium) is a selective and orally active leukotriene receptor antagonist that inhibits the cysteinyl leukotriene CysLT1 receptor

Lukast® inhibits physiologic actions (bronchoconstriction) of LTD4 at the CysLT1 receptor without any agonist activity CysLTs have been correlated with the pathophysiology of asthma and allergic rhinitis

Lukast® also decreases peripheral blood eosinophil counts by 9-15% in asthmatic patients compared to placebo. In patients with seasonal allergic rhinitis **Lukast®** could limit the increase in peripheral blood eosinophil counts to 0.2% compared to 12.5% increase in placebo-treated patients

Indications

- **Lukast®** is indicated for the prophylaxis and chronic treatment of asthma in adults and pediatric patients.
- **Lukast®** is indicated for the relief of symptoms of seasonal allergic rhinitis in adults and pediatric patients 2 years of age and older.

Dosage and administration

Lukast® can be taken without regards to meal, as montelukast is not affected by food

Usual dose in adults and adolescents 15 years of age and older with asthma or seasonal allergic rhinitis

- **One Lukast® 10mg tablet daily.**

Usual pediatric dose for patients with asthma or seasonal allergic rhinitis

- **6 to 14 years of age:** One **Lukast®** 5mg chewable tablet daily.
- **2 to 5 years of age:** One **Lukast®** 4mg chewable tablet daily

Note: -

- The dose should be taken once daily in the evening in patients with asthma alone or combined with seasonal allergic rhinitis, while for seasonal allergic rhinitis alone, the time of administration may be individualized to suit patient needs

Use in pregnancy and lactation

Pregnancy

Pregnancy category B: As there are no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, montelukast should be used during pregnancy only if clearly needed.

Lactation

It is not known if montelukast is excreted in human milk. Because many drugs are excreted in human milk, caution is advised when montelukast is given to a nursing mother

Side effects

Regardless of causality assessment the following side effects were reported in ≥ 1% to 2% of patients with asthma compared to placebo

- In adults and adolescents 15 years of age and older

Fever, fatigue, abdominal pain, trauma, dyspepsia, gastroenteritis, dental pain, dizziness, headache, nasal congestion, cough, influenza, rash, pyuria and increased ALT and AST

- Pediatric patients 6-14 years of age:

Pharyngitis, influenza, fever, sinusitis, nausea, diarrhea, dyspepsia, otitis, viral infection and laryngitis

- Pediatric patients 2-5 years of age

Fever, cough, abdominal pain, diarrhea, headache, rhinorrhea, sinusitis, otitis, influenza, rash, ear pain, gastroenteritis, eczema, urticaria, varicella, pneumonia, dermatitis and conjunctivitis

Precautions

- Montelukast is not indicated for use in the reversal of bronchospasm in acute asthma attacks, including status asthmaticus, so patients are advised to keep appropriate rescue medication available. Therapy with montelukast can be continued during acute exacerbations of asthma
- Patients with known aspirin sensitivity should continue avoidance of aspirin or non steroidal anti-inflammatory agents while taking montelukast
- A causal association between montelukast and systemic eosinophilia presenting with clinical features of vasculitis consistent with Churg Strauss syndrome has not been established
- Patients should be advised to take Montelukast daily as prescribed, even when they are asymptomatic, as well as during periods of worsening asthma.
- Montelukast should not be abruptly substituted for inhaled or oral corticosteroids, and the dose of inhaled corticosteroid should be reduced gradually under medical supervision.
- Montelukast should not be used as monotherapy for the treatment and management of exercise- induced bronchospasm. Patients having exacerbations of asthma after exercise should continue to use their usual regimen of inhaled β-agonists as prophylaxis and have available for rescue a short acting inhaled β agonist.

Drug interactions

- Montelukast has been administered with other therapies routinely used in the prophylaxis and chronic treatment of asthma with no apparent increase in adverse reactions
- It is advised to employ appropriate clinical monitoring when potent cytochrome P450 enzyme inducers such as: Phenobarbital or rifampin, are co administered with montelukast since phenobarbital may decrease the AUC of montelukast by 40% following a single 10mg dose of montelukast. No dosage adjustment for montelukast is recommended.

Contraindications

Hypersensitivity to any component of this product.

Overdosage

No mortality occurred following single oral doses of montelukast up to 5000mg/kg in mice (estimated exposure was 250 times the AUC for adults and children at the maximum recommended daily oral dose), and rats (estimated exposure was 170 times the AUC for adults and children at the maximum recommended daily oral dose).

No specific information is available on the treatment of overdosage with montelukast. Usual supportive measures should be employed, e.g.: removing unabsorbed material from the gastrointestinal tract, employ clinical monitoring and institute supportive therapy, if required

Presentations

Lukast® 10mg Film coated tablets: Montelukast sodium 10.4mg/ tablet. (Available in 30 tab. pack size)
Lukast® 5mg chewable tablets: Montelukast sodium 5.2mg/ tablet. (Available in 30 tab. pack size)
Lukast® 4mg chewable tablets: Montelukast sodium 4.2mg/ tablet. (Available in 30 tab. pack size)

(This is a medicament - keep medicaments out of reach of children)

- **Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.**
- **Follow strictly the doctor's proscription, method for use and the instructions of the pharmacist who sold the medicament .**
- **The doctor and the pharmacist are experts in medicine, its benefits and risks .**
- **Donot by yourself Interrupt the period of treatment prescribed for you.**
- **Do not repeat the same prescription without consulting your doctor**

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