Croma

Montelukast

COMPOSITION

Croma 4 Tablet: Each orodispersible tablet contains 4 mg of Montelukast as Montelukast Sodium USP.

Croma 5 Tablet: Each chewable tablet contains 5 mg of Montelukast as Montelukast Sodium USP.

Croma 10 Tablet: Each film-coated tablet contains 10 mg of Montelukast as Montelukast Sodium USP.

PHARMACOLOGY

Pharmacodynamics:

Montelukast is a selective & competitive leukotriene receptor antagonist that inhibits the cysteinyl leukotriene (CysLT1) to occupy the receptors. The occupation of leukotriene receptors by the cysteinyl leukotriene (CysLT1) has been correlated with the pathophysiology of asthma. Montelukast demonstrates virtually no affinity for adrenergic, histamine, serotonin, muscarinic or prostanoid receptors.

Pharmacokinetics:

Montelukast is rapidly absorbed following oral administration. For the 10 mg film-coated tablet, the mean peak plasma concentration (Cmax) is achieved three 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. For the 5 mg chewable tablet, the Cmax is achieved in two hours after administration in adults in the fasted state. The mean oral bioavailability is 73% and is decreased to 63% by a standard meal. For the 4 mg orodispersible tablet, the mean Cmax is achieved in two hours after administration in pediatric patients 2 to 5 years of age in the fasted state. Montelukast is more than 99% bound to plasma proteins. In vitro studies using human liver microsomes indicate that cytochrome P450 3A4, 2A6 and 2C9 are involved in the metabolism of Montelukast. Montelukast and its metabolites are excreted almost exclusively via the bile.

INDICATIONS

Croma is indicated for the prophylaxis and chronic treatment of asthma and for the relief of symptoms of allergic rhinitis in adults and pediatric patients 6 month of age and older.

DOSAGE & ADMINISTRATION

Croma 4 Tablet: The dosage for pediatric patients 6 months to 5 years of age is one 4 mg orodispersible tablet daily to be taken in the evening. Croma 4 should be taken one hour before or 2 hours after food. No dosages adjustment within this age group is necessary.

Croma 5 Tablet: The dosage for pediatric patients 6 to 14 years of age is one 5 mg chewable tablet daily to be taken in the evening. Croma 5 should be taken one hour before or 2 hours after food. No dosages adjustment within this age group is necessary.

Croma 10 Tablet: The dosage for adults and adolescents 15 years of age and older with asthma and concomitant seasonal allergic rhinitis, is one 10 mg tablet daily to be taken in the evening.

CONTRAINDICATIONS

Montelukast is contraindicated in patients with hypersensitivity to it.

SIDE EFFECTS

Montelukast is usually well-tolerated. However, gastro-intestinal disturbances, dry mouth, thirst; hypersensitivity reactions including anaphylaxis, angioedema and skin reactions; asthenia, dizziness, agitation, restlessness, paraesthesia, headache, sleep disorders (insomnia, drowsiness, abnormal dreams, nightmares); upper respiratory tract infections, fever, arthralgia, myalgia; palpitations, increased bleeding tendency, cholestatic hepatitis, raised serum transaminases, oedema, hallucinations and seizures also reported.

PRECAUTIONS

Montelukast is not indicated for use in the reversal bronchospasm in acute asthma attacks, including status asthmatics. Montelukast should not be abruptly substituted for inhaled or oral corticosteroids. Montelukast should not be used monotherapy for the treatment and management of exercise induced bronchospasm. Patients with known aspirin sensitivity should continue avoidance of aspirin or non-steroidal anti-inflammatory agents while taking Montelukast.

USE IN PREGNANCY AND LACTATION

There are no adequate and well-controlled studies in pregnant women. Montelukast should be used during pregnancy only if clearly needed. Because many drugs are excreted in human milk, caution should be exercised when Montelukast is given to a nursing mother.

USE IN CHILDREN

Safety and efficacy of the use of Montelukast in the children of 6 months to 14 years of age has been supported and established with various well-controlled and sufficient clinical studies. Thereby the safety and efficacy profile of Montelukast in the above mentioned age group is similar to those of adult patients.

DRUG INTERACTIONS

Montelukast may be administered with other therapies routinely used in the prophylaxis and chronic treatment of asthma. In drug-interactions studies, the recommended clinical dose of montelukast did not have clinically important effects on the pharmacokinetics of the following medicinal products: theophylline, prednisone, prednisolone, oral contraceptives (norethindrone 1 mg/ethinyl estradiol 35 mcg), terfenadine, digoxin and warfarin.

Since montelukast is metabolised by CYP 3A4, caution should be exercised, particularly in children, when montelukast is co-administered with inducers of CYP 3A4, such as phenytoin, phenobarbital and rifampicin.

STORAGE

Store in a cool and dry place, protected from light. Keep out of the reach of children.

PACKAGING

Croma 4 tablet: Each box contains 3x10 orodispersible tablets in blister pack.

Croma 5 tablet: Each box contains 3x10 chewable tablets in blister pack.

Croma 10 tablet: Each box contains 3x10 film-coated tablets in blister pack.

Manufactured by:

SHARIF PHARMA

Sharif Pharmaceuticals Ltd.

Rupganj, Narayanganj, Bangladesh

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