DUO AIR®

Levocetirizine Dihydrochloride 5 mg & Montelukast 10 mg Tablets

Composition:

Each film coated tablet contains:

Levocetirizine Dihydrochloride USP	5 mg.
Montelukast Sodium USP eq. to Montelukast	10 mg.
Excipients	Q.S.

Colour : Ferric oxide yellow USNF, Ferric oxide red USNF

PHARMACODYNAMICS:

Pharmacotherapeutic group:

Montelukast:- Leukotriene receptor antagonists
Levocetirizine:- Antihistamine

ATC code:
Montelukast:- R03D C03
Levocetirizine:- R06A E09

Mechanism of action:
Montelukast:- Montelukast works by blocking the action of leukotriene D4 in the lungs resulting in decreased inflammation and relaxation of smooth muscle.
Levocetirizine:- Levocetirizine is an antihistamine. It acts as an inverse agonist that decreases activity at histamine H1 receptors. This in turn prevents the release of other allergy chemicals and increase the blood supply to the area.

PHARMACOKINETICS:
Montelukast:-
Absorption:-
Montelukast is rapidly absorbed following oral administration. For the 10 mg, 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. Safety and efficacy were demonstrated in clinical trials where the 10 mg film-coated tablet was administered without regard 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 metabolised. In studies with therapeutic doses, plasma concentrations of metabolites of montelukast are undetectable at steady state in adults and children.

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.

Levocetirizine:-

Absorption:-
Levocetirizine is rapidly and extensively absorbed following oral administration. Peak plasma concentrations are achieved 0.9 h after dosing.

Distribution:-
No tissue distribution data are available in humans, neither concerning the passage of levocetirizine through the blood-brain-barrier.

Biotransformation:-
The extent of metabolism of levocetirizine in humans is less than 14% of the dose and therefore differences resulting from genetic polymorphism or concomitant intake of enzyme inhibitors are expected to be negligible.

Elimination:-
The plasma half-life in adults is 7.9 ± 1.9 hours. The half-life is shorter in small children. The mean apparent total body clearance is 0.63 ml/min/kg. The major route of excretion of levocetirizine and metabolites is via urine, accounting for a mean of 85.4% of the dose.

INDICATIONS:
Montelukast and Levocetirizine tablets is used for sneezing and runny nose due to allergies, Hay fever and Allergic skin conditions.

RECOMMENDED DOSE:
Adults and adolescents (>15 years):- 1 tablet once daily.
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.

METHOD OF ADMINISTRATION:
For oral use.

CONTRAINDICATIONS:
Hypersensitivity to the active substance or to any of the excipients used in the formulation.

WARNING AND PRECAUTIONS:
Montelukast:-
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 β-agonist should be used. Montelukast should not be abruptly substituted for inhaled or oral corticosteroids.

Levocetirizine:-
Precaution is recommended with concurrent intake of alcohol.
Caution should be taken in patients with predisposing factors of urinary retention (e.g. spinal cord lesion, prostatic hyperplasia) as levocetirizine may increase the risk of urinary retention.Caution should be taken in patients with epilepsy and patients at risk of convulsion as levocetirizine may cause seizure aggravation.

INTERACTIONS WITH OTHER MEDICAMENTS:

Montelukast:-
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 (ethinyl estradiol/ norethindrone 35/1), terfenadine, digoxin and warfarin.

Levocetirizine:-
No interaction studies have been performed with levocetirizine (including no studies with CYP3A4 inducers); studies with the racemate compound cetirizine demonstrated that there were no clinically relevant adverse interactions (with antipyrine, azithromycin, cimetidine, diazepam, erythromycin, glipizide, ketoconazole andpseudoephedrine).

PREGNANCY AND LACTATION:
Montelukast:-

Pregnancy:-
Montelukast 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 may be used in breast-feeding only if it is considered to be clearly essential

Levocetirizine:-

Pregnancy:-
There are no or limited amount of data from the use of levocetirizine in pregnant women.
Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development. The use of Levocetirizine may be considered during pregnancy, if necessary.

Lactation:-
Cetirizine, the racemate of levocetirizine, has been shown to be excreted in human. Therefore, the excretion of levocetirizine in human milk is likely. Adverse reactions associated with levocetirizine may be observed in breastfed infants. Therefore, caution should be exercised when prescribing levocetirizine to lactating women.

UNDESIRABLE EFFECTS:

Montelukast:-
Headache, abdominal pain, hallucinations, disorientation, suicidal thinking and behaviour (suicidality), Dysphemia, diarrhoea, nausea, vomiting, pyrexia.

Levocetirizine:-
Headache, Somnolence, Mouth dry, Fatigue, Diarrhoea, Vomiting, Constipation, Sleep disorder.

OVERDOSE AND TREATMENT:

Montelukast:-
No specific information is available on the treatment of overdose with montelukast. 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.

Levocetirizine:-
Symptoms
Symptoms of overdose may include drowsiness in adults. In children, agitation and restlessness may initially occur, followed by drowsiness in children.

Management of overdoses
There is no known specific antidote to levocetirizine.
Gastric lavage should be considered shortly after ingestion of the drug.
Levocetirizine is not effectively removed by haemodialysis.

STORAGE CONDITION:
Store below 30° C.
Protect from light & moisture.

DOSAGE FORM AND PACKAGING AVAILABLE
DOSAGE FORM: Tablet
PACKAGING: 2 x 15 Alu-Alu blister

Marketed by:

PYXUS

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