Bosch

For Medical Professional only

ALOC® Tablets Capsules

(Fexofenadine HCl)

الوک ٹیبلیٹس/کیپسولز

(فیکسوفیناڈین ہائیڈروکلورائیڈ)

DESCRIPTION:
Fexofenadine hydrochloride, the active ingredient of ALOC, is a histamine H1-receptor antagonist with the chemical name (±)-4-[1 hydroxy-4-[4- (hydroxydiphenylmethyl)-1- piperidinyl] -butyl] -α, α-dimethyl benzeneacetic acid hydrochloride. The molecular weight is 538.13 and the empirical formula is $C_{32}H_{39}NO_4$•HCl.

COMPOSITION:
ALOC 60mg Capsules:
Each capsule contains:
Fexofenadine HCl U.S.P. 60mg
(Product Specs.: U.S.P.)
"Product Contains Lactose"

ALOC 120mg Tablets:
Each film coated tablet contains:
Fexofenadine HCl U.S.P. 120mg
(Product Specs.: U.S.P.)

ALOC 180mg Tablets:
Each film coated tablet contains:
Fexofenadine HCl U.S.P. 180mg
(Product Specs.: U.S.P.)

CLINICAL PHARMACOLOGY:
Pharmacodynamic Properties:
Pharmacotherapeutic group: Antihistamines for systemic use, ATC code: R06A X26.

Mechanism of Action:
Fexofenadine hydrochloride is a non-sedating H1 antihistamine. Fexofenadine is a pharmacologically active metabolite of terfenadine.

Pharmacokinetic Properties
Absorption:
Fexofenadine hydrochloride is rapidly absorbed into the body following oral administration, with Tmax occurring at approximately 1-3 hours post dose.

Distribution:
Fexofenadine hydrochloride is 60% to 70% bound to plasma proteins, primarily albumin and α_1-acid glycoprotein.

Metabolism:
Approximately 5% of the total dose of fexofenadine hydrochloride was eliminated by hepatic metabolism.

Elimination:
Elimination half-life of about 14 hours has been reported although this may be prolonged in patients with renal impairment. Excretion is mainly in the faeces with only 10% being present in the urine.

SPECIFIC POPULATIONS
Renal Insufficiency
In patients with mild to moderate (creatinine clearance 41-80mL/min) and severe (creatinine clearance 11-40mL/min) renal impairment, peak plasma levels of fexofenadine HCl were 87% and 111% greater, respectively, and mean elimination half-lives were 59% and 72% longer, respectively, than observed in normal subjects.

Elderly:
In older subjects (>65 years old), peak levels of fexofenadine HCl were 99% greater than those observed in normal subjects (<65 years old). Mean elimination half-life was similar to those

observed in normal subjects.

THERAPEUTIC INDICATIONS:
Seasonal Allergic Rhinitis
ALOC is indicated for the relief of symptoms associated with seasonal allergic rhinitis in adults and children 2 years of age and older.

Chronic Idiopathic Urticaria
ALOC is indicated for treatment of uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 months of age and older.

DOSAGE AND ADMINISTRATION:
Seasonal Allergic Rhinitis
Adults and Children 12 Years and Older:
The recommended dose of ALOC (Fexofenadine HCl) is 60mg twice daily, or 180mg once daily.

Children 6 to 11 Years:
The recommended dose of ALOC (Fexofenadine HCl) is 30mg twice daily. A dose of 30mg once daily is recommended as the starting dose in pediatric patients with decreased renal function.

Chronic Idiopathic Urticaria
Adults and Children 12 Years and Older:
The recommended dose of ALOC (Fexofenadine HCl) is 60mg twice daily. A dose of 60mg once daily is recommended as the starting dose in patients with decreased renal function.

Children 6 to 11 Years:
The recommended dose of ALOC (Fexofenadine HCl) is 30mg twice daily. A dose of 30mg once daily is recommended as the starting dose in pediatric patients with decreased renal function.

Patients with Renal Impairment:
In patients with decreased renal function the recommended dose of ALOC (Fexofenadine HCl) is 60mg once daily as the starting dose.

In pediatric patients with decreased renal function the recommended dose of ALOC (Fexofenadine HCl) is 30mg once daily as the starting dose.

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

WARNINGS AND PRECAUTIONS:
As with most new medicinal products there is only limited data in the elderly and renally or hepatically impaired patients. Fexofenadine hydrochloride should only be administered in these special groups on the advice of a doctor.

Patients with a history of or ongoing cardiovascular disease should be warned that, antihistamines as a medicine class, have been associated with the adverse reactions, tachycardia and palpitations.

DRUG INTERACTIONS:
Fexofenadine does not undergo hepatic biotransformation and therefore will not interact with other medicinal products through hepatic mechanisms. Coadministration of fexofenadine hydrochloride with erythromycin or ketoconazole has been found to result in a 2-3 times increase in the level of fexofenadine in plasma. The changes were not accompanied by any effects on the QT interval and were not associated with any increase in adverse reactions compared to the medicinal products given singly.
Animal studies have shown that the increase in plasma levels of fexofenadine observed after coadministration of erythromycin or ketoconazole, appears to be due to an increase in gastrointestinal absorption and either a decrease in biliary excretion or gastrointestinal secretion, respectively.
No interaction between fexofenadine and omeprazole was observed. However, the administration of an antacid containing aluminium and magnesium hydroxide gels 15 minutes prior to fexofenadine hydrochloride caused a reduction in bioavailability, most likely due to binding in the gastrointestinal tract. It is advisable to leave 2 hours between administration of fexofenadine hydrochloride and aluminium and magnesium hydroxide containing antacids.

ADVERSE EFFECTS:
Headache, drowsiness, dizziness, nausea, fatigue, hypersensitivity reactions with manifestations such as angioedema, chest tightness, dyspnoea, flushing and systemic anaphylaxis, Insomnia, nervousness, sleep disorders or nightmares/excessive dreaming (paroniria), Tachycardia, palpitations, Diarrhoea, Rash, urticaria, pruritus.

USE IN PREGNANCY AND LACTATION:
Pregnancy:
Fexofenadine HCl should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation:
Because many drugs are excreted in human milk, caution should be exercised when fexofenadine HCl is administered to a nursing woman.

OVERDOSE:
Dizziness, drowsiness, fatigue and dry mouth have been reported with overdose of fexofenadine hydrochloride. Single doses up to 800 mg, and doses up to 690 mg twice daily for 1 month, or 240 mg once daily for 1 year have been administered to healthy subjects without the development of clinically significant adverse reactions as compared with placebo. The maximum tolerated dose of fexofenadine hydrochloride has not been established.

Standard measures should be considered to remove any unabsorbed medicinal product. Symptomatic and supportive treatment is recommended. Haemodialysis does not effectively remove fexofenadine hydrochloride from blood.

SHELF LIFE:
3 years

INSTRUCTIONS:
Protect from heat, sunlight & moisture, store below 30°C.
The expiration date refer to the product correctly stored at the required condition.
Keep out of the reach of children.
Patients and healthcare professionals can also report suspected adverse drug reaction at ade@bosch-pharma.com.
To be sold on prescription of a registered medical practitioner only.

PRESENTATION:
ALOC 60mg capsules : Each Cold Form & Cold Seal pack contains 10's capsules.
ALOC 120mg tablets : Each Cold Form & Cold Seal pack contains 10's tablets.
ALOC 180mg tablets : Each Cold Form & Cold Seal pack contains 10's tablets.

ہدایات:
دھوپ، گرمی اور نمی سے محفوظ ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
بچوں کی پہنچ سے دُور رکھیں۔
صرف مستند ڈاکٹر کے نسخے پر فروخت کے لئے۔

Manufactured by:
Bosch Pharmaceuticals (Pvt) Ltd.
221-223, Sector 23, Korangi Industrial Area,
Karachi - Pakistan

Bosch

For Medical Professional only

ALOC® Tablets Capsules

(Fexofenadine HCl)

الوک ٹیبلیٹس/کیپسولز

(فیکسوفیناڈین ہائیڈروکلورائیڈ)

FIRST & ONLY CERTIFIED HALAAL

HALAAL

PHARMACEUTICAL COMPANY