Name of the product: Fescot Tablets
Size of the insert:
Specification (7x5.5)inches

Fescot Tablets

فیسکوٹ ٹیبلٹس

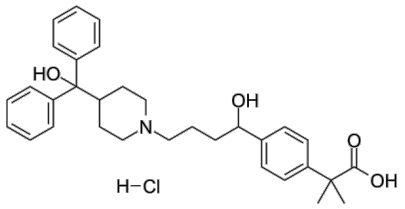
COMPOSITION:

Each Film Coated Tablet Contains

Fexofenadine Hydrochloride BP/USP: 60mg, 120mg & 180mg

DESCRIPTION:

Fexofenadine hydrochloride, the active ingredient of FESCOT tablets, 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. It has the following chemical structure;



CLINICAL PHARMACOLOGY:

Mechanism of Action:

Fexofenadine hydrochloride, the major active metabolite of terfenadine, is an antihistamine with selective H1-receptor antagonist activity. Both enantiomers of fexofenadine hydrochloride displayed approximately equipotent antihistaminic effects.

Pharmacodynamics:

Wheal and Flare: Human histamine skin wheal and flare studies in adults following single and twice daily doses of 20 and 40 mg fexofenadine hydrochloride demonstrated that the drug exhibits an antihistamine effect by 1 hour, achieves maximum effect at 2 to 3 hours, and an effect is still seen at 12 hours. There was no evidence of tolerance to these effects after 28 days of dosing.

Pharmacokinetics: The pharmacokinetics of fexofenadine hydrochloride in subjects with seasonal allergic rhinitis and subjects with chronic urticaria were similar to those in healthy subjects.

Absorption:

Fexofenadine hydrochloride was absorbed following oral administration of a single dose of two 60 mg capsules to healthy male subjects with a mean time to maximum plasma concentration occurring at 2.6 hours post-dose. After administration of a single 60 mg capsule to healthy adult subjects, the mean maximum plasma concentration (Cmax) was 131 ng/mL. Following single dose oral administrations of either the 60 and 180 mg tablet to healthy adult male subjects, mean Cmax were 142 and 494 ng/mL, respectively. Fexofenadine hydrochloride pharmacokinetics are linear for oral doses up to a total daily dose of 240 mg (120 mg twice daily).

Distribution: Fexofenadine hydrochloride is 60% to 70% bound to plasma proteins, primarily albumin and α1-acid glycoprotein.

Metabolism: Approximately 5% of the total dose of fexofenadine hydrochloride

was eliminated by hepatic metabolism.

Elimination: The mean elimination half-life of fexofenadine was 14.4 hours following administration of 60 mg twice daily in healthy adults.

INDICATIONS AND USAGE:

FESCOT is an H1-receptor antagonist indicated for:

- Relief of symptoms associated with seasonal allergic rhinitis in patients ≥ 2 years of age.
- Treatment of uncomplicated skin manifestations of chronic idiopathic urticaria in patients ≥ 6 month of age.

DRUG INTERACTIONS:

- ***Antacids:*** Do not take at the same time as aluminum and magnesium containing antacids.
- ***Erytromycin & Ketoconazole:*** Ketoconazole or erythromycin led to increased plasma concentrations of fexofenadine.
- ***Fruit juice:*** Take with water; not fruit juice.

CONTRAINDICATIONS:

Patients with known hypersensitivity to fexofenadine and any of the ingredients of FESCOT.

ADVERSE REACTIONS:

The most common adverse reactions (≥ 2%) in subjects age 12 years and older were headache, back pain, dizziness, stomach discomfort, and pain in extremity. In subjects aged 6 to 11 years, cough, upper respiratory tract infection, pyrexia and otitis media were more frequently reported. In subjects aged 6 months to 5 years, vomiting, diarrhea, somnolence/fatigue and rhinorrhea were more frequently reported. Other adverse reactions have been reported.

USE IN SPECIFIC POPULATIONS:

- ***Pregnancy:*** Use only if benefit justifies risk to fetus.
- ***Nursing Mothers:*** Use with caution.

DOSAGE AND ADMINISTRATION:

Patient Population	FESCOT Tablets
Adults and children ≥ 12 years	60 mg twice daily[1], or 180 mg once daily[2]
Children 6 to 11 years	30 mg twice daily[1]
Children 2 to 5 years	N/A
Children 6 months to less than 2 years	N/A

[1] starting dose in patients with decreased renal function should be the recommended dose indicated above but administered once daily.

[2] dose not for use in patients with decreased renal function.

STORAGE & PRECAUTIONS:

Store in cool, dry and dark place below 25°C. Keep all medicines out of reach of children. To be sold and used on the prescription of Registered Medical Practitioners only.

PRESENTATION:

Fescot 60mg, 120mg & 180mg film coated tablets are available in packing containing 10 film coated tablets.

عمومی خوراک: ڈاکٹر کی ہدایت کے مطابق۔

احتیاط: دوا صرف مستند ڈاکٹر کے زیر ہدایت استعمال کریں۔ روشنی، نمی اور گرمی سے بچائیں۔ 25 ڈگری سینٹی گریڈ سے کم درجہ حرارت پر محفوظ کریں۔ تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

Complete Medical Information available only for doctors on request.

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Manufactured by: **SCOTMANN PHARMACEUTICALS**
5-D, I-10/3 Industrial Area, Islamabad-Pakistan.
www.scotmann.com