For the use only of Registered Medical Practitioner or a Hospital or a Laboratory.

ALERNIL®

एलर्निल

Fexofenadine Hydrochloride

Drug Category: Anti-histamines
Composition : Each film coated tablet contains Fexofenadine 120/180 mg
Presentation : 10 Tablets x 10 Blisters

MOLECULAR INTRODUCTION:
Fexofenadine Hydrochloride (**ALERNIL**) is a second generation selective non-sedating antihistamine indicated for the relief of symptoms associated with seasonal allergic rhinitis. It is a competitive peripheral selective histamine H1 receptor antagonist on effector cells in the GIT, blood vessels and the respiratory tract.

Unlike antihistamines of the first generation, Fexofenadine does not readily cross the blood brain barrier and therefore does not produce sedation or impair psychomotor performance; and is free of atropinic side effects. It has been described as both second and third-generation antihistamine.

Fexofenadine is the predominant active metabolite of Terfenadine (an older antihistaminic agent with potentially serious contraindications), which was found to metabolize into the related carboxylic acid, Fexofenadine. Fexofenadine was found to retain all of the biological activity of its parent molecule while giving fewer adverse reactions in patients; which led to the subsequent replacement of Terfenadine in the market by its active metabolite - FEXOFENADINE.

INDICATIONS:
Fexofenadine is clinically effective in the treatment of Seasonal Allergic Rhinitis and Chronic Idiopathic Urticaria for which it is a suitable option for FIRST-LINE THERAPY.

Seasonal Allergic Rhinitis
Fexofenadine is used to relieve the allergy symptoms of seasonal allergic rhinitis ('hay fever'), including runny nose; sneezing; red, itchy or watery eyes; or itching of the nose, throat or roof of the mouth. **[Dose: 120 mg daily]**

Chronic Idiopathic Urticaria
Fexofenadine is indicated for the treatment of uncomplicated skin manifestations of chronic idiopathic urticaria (hives; red, itchy raised areas of the skin), including itching and rash.
[Dose: 180 mg daily]

Other Allergic manifestations of the Skin and Respiratory tract

MECHANISM OF ACTION:
Fexofenadine works against the naturally occurring chemical histamine in the body. Histamine is produced as part of the body's defense mechanism and is responsible for many of the signs and symptoms of allergic reactions. Histamine is released from the histamine-storing cells (mast cells) in response to a foreign substance (known as an allergen), and then attaches to other cells that have receptors for histamine.

The attachment of histamine to the receptors causes the cell to be "activated," releasing other chemicals that produce the effects associated with allergy. Fexofenadine blocks one type of receptor for histamine (the H1 receptor) and thus prevents the activation of H1 receptor-containing cells by histamine. It does not prevent the actual release of histamine from mast cells, but prevents it from binding to its receptors.

PHARMACOKINETICS:
Fexofenadine is rapidly absorbed (onset of relief < or = 2 hours) and has a long duration of action (about 24 hours), making it suitable for once daily administration. It is 60% to 70% bound to plasma proteins, primarily albumin and α1-acid glycoprotein. The mean elimination half-life was 14.4 hours (11-16 hours) following twice daily administration of 60mg in healthy adult subjects.

SIDE EFFECTS:
Stomach upset, menstrual cramps, back pain, cough, fever, stuffy nose, earache or dizziness may occur. This medication does not usually cause drowsiness when used at recommended doses and under normal circumstances. However, this drug may cause dizziness.

CONTRAINDICATIONS
Individuals demonstrating hypersensitivity to fexofenadine or any components of its
formulation.

DRUG INTERACTIONS
CYP3A3/4 enzyme substrate.
In two separate studies, fexofenadine 120 mg twice daily (high doses) was coadministered with standard doses of erythromycin or ketoconazole to healthy volunteers and although fexofenadine peak plasma concentrations increased, no differences in adverse events or QTc intervals were observed. It remains unknown if a similar interaction occurs with other azole antifungal agents (eg, itraconazole) or other macrolide antibiotics (eg, clarithromycin).

Manufactured by:
Deurali-Janta Pharmaceuticals Pvt. Ltd.
679, Budhanilkantha Sadak, Bansbari - 03 | G.P.O. Box: 4239, Kathmandu, Nepal
Tel: +977-01- 4018777 | E-mail: mplanning@deuralijanta.com
Website: www.deuralijanta.com

01 pi ALT 20