FENADEX®

DESCRIPTION

FENADEX is the trademark of Fexofenadine Hydrochloride, a non-sedating H1-receptor antihistamine. Each **FENADEX 60**, **120** and **180** Tablet contains Fexofenadine Hydrochloride 60, 120 and 180mg, respectively.

CHEMISTRY

Fexofenadine Hydrochloride is: α,α-dimethyl-4-[1-hydroxy-4-[4-(hydroxydiphenylmethyl)-1-piperidinyl]butyl]benzene acetic acid hydrochloride.

CLINICAL PHARMACOLOGY

FENADEX (Fexofenadine) is a non-sedating antihistamine that selectively antagonizes peripheral H1-receptor activity. Fexofenadine has been found to inhibit antigen-induced bronchospasm in sensitized guinea pigs and histamine release from peritoneal mast cells in rats. Fexofenadine does not induce cardiotoxicity and is minimally metabolized in the liver by the cytochrome P-450 microsomal enzyme system. Accordingly, Fexofenadine has an increased safety profile compared with the parent drug terfenadine.

Fexofenadine is rapidly absorbed after oral administration and is 60 to 70% bound to plasma proteins. It does not cross the blood brain barrier. About 5% of total dose is metabolized; and approximately 80% and 11% of Fexofenadine is excreted in the feces and urine, respectively.

INDICATIONS

- Treatment of seasonal allergic rhinitis: **FENADEX** is indicated to relieve symptoms that are associated with seasonal allergic rhinitis, such as sneezing, rhinorrhea, red-watery eyes and itchy eyes, nose, and throat.
- Treatment of chronic idiopathic urticaria: **FENADEX** is indicated for the treatment of uncomplicated skin manifestations of chronic idiopathic urticaria. It significantly reduces pruritus and the number of wheals.

DOSAGE

Usual adult dose

- Seasonal allergic rhinitis: **FENADEX** 60mg twice daily, **FENADEX** 120mg once daily, or **FENADEX** 180mg once daily.
- Chronic idiopathic urticaria: **FENADEX** 60mg twice daily, **FENADEX** 120mg once daily, or **FENADEX** 180mg once daily.

Usual pediatric dose

- Children 12 years and older: Same as usual adult dose.
- Children 6 to 11 years: **FENADEX** 30mg (one-half **FENADEX 60** Tablet) twice daily.

Notes

- The usual adult and adolescent prescribing limit is 180mg daily or 60mg two times a day. The usual pediatric prescribing limit is 30mg twice daily.
- For adult patients with decreased renal function, an initial dose of 60mg once daily is recommended.
- For pediatric patients with decreased renal function, an initial dose of 30mg once daily is recommended.
- For children under 6 years, safety and efficacy have not been established.

ADVERSE EFFECTS

Less frequent effects: Drowsiness, dysmennorhea, dyspepsia, fatigue, back pain, dizziness, headache, nausea, sinusitis, and viral infections such as cold and flu. In pediatrics, less frequent effects also include coughing, fever, and otitis media.

Rare effects: Anaphylaxis and hypersensitivity reactions to Fexofenadine.

USE IN PREGNANCY

Studies in rats and rabbits using oral terfenadine dosage up to 300 mg/kg (resulting in plasma Fexofenadine concentrations 4 and 37 times the human therapeutic value, respectively, based on Fexofenadine dosage of 60mg twice daily) have not revealed evidence of teratogenicity. In rats given oral doses of terfenadine ≥ 150 mg/kg, dose-related decreases in pup weight and survival were observed. No adequate or well-controlled studies have been done in humans. Fexofenadine should be used during pregnancy only when the potential benefits justify the possible risks to the fetus. FDA Pregnancy Category C.

USE IN LACTATION

The distribution of Fexofenadine into breast milk is not known. The drug should be used with caution in nursing women, and a decision should be made whether to discontinue nursing or Fexofenadine, taking into account the importance of the drug to the woman.

INTERFERENCE WITH CLINICAL AND LABORATORY TESTS

Although the effect of Fexofenadine on antigen skin-testing procedures has not been fully elucidated, the drug should be discontinued 24 to 48 hours before performing antigen skin-testing procedures.

DRUG INTERACTIONS

- The use of Fexofenadine with erythromycin or ketoconazole may increase plasma concentrations of Fexofenadine without resulting in any clinically important adverse effects or changes in QT interval.
- Aluminum and magnesium hydroxide-containing antacids may decrease Fexofenadine absorption. It is advisable to leave 2 hours between the administration of Fexofenadine and these agents.

CONTRAINDICATIONS

Hypersensitivity to Fexofenadine.

WARNINGS

Based upon increases in the bioavailability and half-life of Fexofenadine, once-daily administration is recommended initially in patients with impaired renal function (see Dosage).

OVERDOSE

Effects of Fexofenadine overdose include dizziness, drowsiness, and dry mouth.

In case of Fexofenadine overdose, unabsorbed drug should be removed from the gastrointestinal tract by usual measures. Supportive and symptomatic treatment should then be started. Fexofenadine is not effectively removed from the blood by hemodialysis.

PRECAUTIONS

Not documented.

HOW SUPPLIED

- Boxes of 30 blistered **FENADEX 60** Tablets.
- Boxes of 15 blistered **FENADEX 120** Tablets.
- Boxes of 15 blistered **FENADEX 180** Tablets.
- Hospital packs of different presentations.

Store away from children ,at a tmeperture between 15 and 30 C,protect from humidity.
Do not use after the expiry date shown on the package .

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medicament.
- The doctor and the pharmacist are experts in medicine.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicaments out of the reach of children.

Issued in July 2004

COUNCIL OF ARAB HEALTH MINISTERS
UNION OF ARAB PHARMACISTS

Prescribing Information Available Upon Request

THE JORDANIAN PHARMACEUTICAL MANUFACTURING CO. (P.L.C)
P.O. BOX 94, NAOR 11710, JORDAN