United Pharmaceuticals

EXOFEN®

Fexofenadine HCl

Description:

EXOFEN® (Fexofenadine hydrochloride) is the active metabolite of terfenadine, which is a selective peripheral H_1 antihistamine, with rapid, long-lasting activity which does not have sedative and anti-cholinergic effects at the recommended dosage.

Clinical trials have shown no evidence of cardio-toxicity even at doses higher than those recommended.

Properties:

After oral administration, Fexofenadine is rapidly absorbed, and shows 60 - 70% binding to plasma proteins. Fexofenadine is not metabolized in the liver.

Excretion of Fexofenadine is mainly in the bile with 10% of the administered dose found as unchanged drug in the urine.

Fexofenadine elimination half-life is 11 - 15 hours after repeated doses.

Indications:

EXOFEN® 120 mg: Symptomatic treatment of seasonal allergic rhinitis in adults and children over 12 years old.

EXOFEN® 180 mg: Symptomatic treatment of pruritus associated with chronic urticaria in adults and children over 12 years old.

Dosage and administration:

Adults and children aged 12 years and over:

EXOFEN® 120 mg: 120 mg per day as a single daily dose (one **EXOFEN® 120 mg** tablet once daily).

EXOFEN® 180 mg: 180 mg per day as a single daily dose (one **EXOFEN® 180 mg** tablet once daily).

Contraindications:

• Patient with known hypersensitivity to any of the ingredients.

• Children under 12 years old, since safety and efficacy have not been established in this age group.

Precautions:

Fexofenadine should be administered with caution in elderly and renally or hepatically impaired adult patients, as with most new drugs there is only limited data.

Use during pregnancy and lactation:

Pregnancy category **C**

As a precautionary measure, Fexofenadine should preferably not be used during pregnancy.

Animal studies have shown no evidence of teratogenic activity. In the absence of teratogenic activity in animals, fetal malformation in humans is not to be expected. There are no relevant clinical data by which to evaluate the potential of Fexofenadine to induce fetal malformation or toxicity when used

during pregnancy.
The use of Fexofenadine by breast-feeding women is inadvisable. There is no data concerning excretion of Fexofenadine in human breast milk. However, Fexofenadine was detected in breast milk after administration of terfenadine to breast-feeding women.

Drug interactions:

Associations requiring precaution for use:

Antacids: Decreased gastrointestinal absorption of Fexofenadine. Antacids should not be taken at the same time as Fexofenadine (at least 2 hours apart, if possible).

Associations to be taken into consideration:

• Erythromycin: Increased bioavailability due to increased intestinal absorption and decreased biliary clearance.

• Ketoconazole: Increased bioavailability due to increased intestinal absorption and decreased gastrointestinal secretion.

Patient notes:

• No interaction clinically significant was observed (i.e. effect on the QT interval) after co-administration of Fexofenadine with Erythromycin or Ketoconazole.

•The variations reported appear to be due only to a pharmacokinetic mechanism with an increase in the bioavailability of Fexofenadine.

Side effects:

In controlled clinical trials the most commonly reported side effects were headache, drowsiness, nausea and dizziness, the incidence of these side effects observed with Fexofenadine was similar to that observed with placebo.

Rare cases of rashes, urticaria, pruritus and hypersensitivity reactions including angioedema, chest tightness, dyspnoea, flushing and systemic anaphylaxis have been reported.

Overdosage:

Measures to taken in cases of massive intoxication:

• Symptomatic treatment.

• Monitoring of vital signs.

Fexofenadine is not dialyzable. There is no known antidote.

Storage conditions:

EXOFEN® 120: Store up to 30ºC.

EXOFEN® 180: Store up to 30ºC.

Presentation:

EXOFEN® 120: Each film coated tablet contains 120 mg Fexofenadine HCl in packs of 15 tablets.

EXOFEN® 180: Each film coated tablet contains 180 mg Fexofenadine HCl in packs of 15 tablets.

Hospital packs are also available.

This is a medicament

- 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 sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicament out of the reach of children.

COUNCIL OF ARAB HEALTH MINISTERS
UNION OF ARAB PHARMACISTS

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