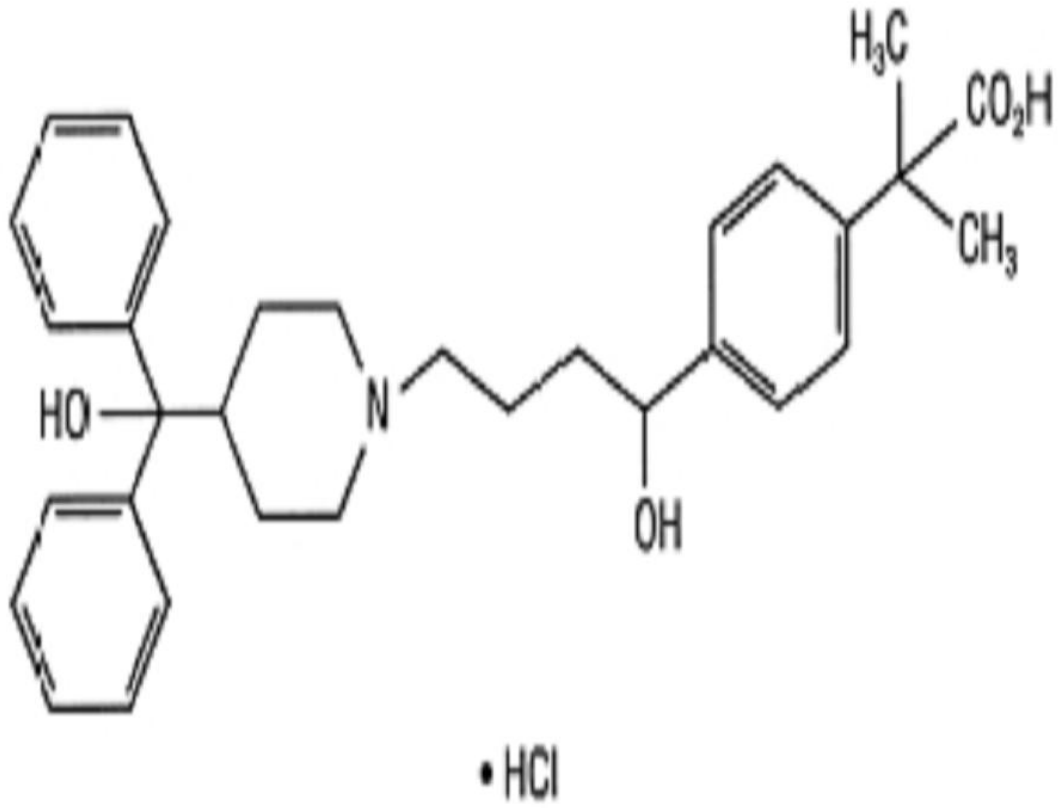
FEXOFENADINE HYDROCHLORIDE - fexofenadine hydrochloride tablet
REMEDYREPACK INC.

DESCRIPTION

Fexofenadine hydrochloride is a histamine H1-receptor antagonist with the chemical name (benzeneacetic acid hydrochloride. It has the following chemical structure:



C32H39NO4Molecular Weight: 538.13

Fexofenadine hydrochloride is a white to off-white crystalline powder. It is freely soluble in methanol and ethanol, slightly soluble in chloroform and water, and insoluble in hexane. Fexofenadine hydrochloride is a racemate and exists as a zwitterion in aqueous media at physiological pH. Fexofenadine hydrochloride tablets for oral administration contains 30, 60, or 180 mg fexofenadine hydrochloride (depending on the dosage strength). The inactive ingredients are as follows: calcium stearate, colloidal silicon dioxide, crospovidone, FD&C red no. 40, FD&C yellow no. 6, hypromellose, polyethylene glycol, polysorbate 80, povidone, powdered cellulose, and titanium dioxide.

CLINICAL PHARMACOLOGY

Mechanism of Action:

Fexofenadine hydrochloride is an antihistamine with selective peripheral H1-receptor antagonist activity. Both enantiomers of fexofenadine hydrochloride displayed approximately equipotent antihistaminic effects. Fexofenadine inhibited histamine release from peritoneal mast cells in rats. In laboratory animals, no anticholinergic, alpha1-adrenergic or beta-adrenergic-receptor blocking effects were observed. No sedative or other central nervous system effects were observed. Radiolabeled

tissue distribution studies in rats indicated that fexofenadine does not cross the blood-brain barrier.

PHARMACOKINETICS

Absorption:
Fexofenadine hydrochloride was rapidly absorbed following oral administration of a single dose of two 60 mg capsules to healthy male volunteers 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 subjects, the mean maximum plasma concentration was 131 ng/mL. Following single dose oral administrations of either the 60 and 180 mg tablet to healthy, adult male volunteers, mean maximum plasma concentrations were 142 and 494 ng/mL, respectively. The tablet formulations are bioequivalent to the capsule when administered at equal doses. Fexofenadine hydrochloride pharmacokinetics are linear for oral doses up to a total daily dose of 240 mg (120 mg twice daily). The administration of the 60 mg capsule contents mixed with applesauce did not have a significant effect on the pharmacokinetics of fexofenadine in adults.

Distribution:
Fexofenadine hydrochloride is 60% to 70% bound to plasma proteins, primarily albumin andglycoprotein.

Elimination:
The mean elimination half-life of fexofenadine was 14.4 hours following administration of 60 mg, twice daily, in normal volunteers.
Human mass balance studies documented a recovery of approximately 80% and 11% of the [14C] fexofenadine hydrochloride dose in the feces and urine, respectively. Because the absolute bioavailability of fexofenadine hydrochloride has not been established, it is unknown if the fecal component represents unabsorbed drug or the result of biliary excretion.

Metabolism:
Approximately 5% of the total oral dose was metabolized.

Special Populations:
Special population pharmacokinetics (for geriatric subjects, renal and hepatic impairment), obtained after a single dose of 80 mg fexofenadine hydrochloride, were compared to those for normal subjects from a separate study of similar design. While subject weights were relatively uniform between studies, these adult special population patients were substantially older than the healthy, young volunteers. Thus, an age effect may be confounding the pharmacokinetic differences observed in some of the special populations.

Seasonal allergic rhinitis (SAR) and chronic idiopathic urticaria (CIU) patients:
The pharmacokinetics of fexofenadine hydrochloride in seasonal allergic rhinitis and chronic idiopathic urticaria patients were similar to those in healthy subjects.

Geriatric Subjects:
In older subjects (65 years old), peak plasma levels of fexofenadine were 99% greater than those observed in normal volunteers (<65 years old). Mean elimination half-lives were similar to those observed in normal volunteers.

Pediatric Patients:
Cross study comparisons indicated that fexofenadine hydrochloride area under the curve (AUC) following oral administration of a 60 mg dose to 7-12 year old pediatric allergic rhinitis patients was 56% greater compared to healthy adult subjects given the same dose. Plasma exposure in pediatric patients given 30 mg fexofenadine hydrochloride is comparable to adults given 60 mg.

Renal Impairment:
In patients with mild to moderate (creatinine clearance 41-80 mL/min) and severe (creatinine clearance 11-40 mL/min) renal impairment, peak plasma levels of fexofenadine were 87% and 111% greater, respectively, and mean elimination half-lives were 59% and 72% longer, respectively, than observed in normal volunteers. Peak plasma levels in patients on dialysis (creatinine clearance10 mL/min) were 82% greater and half-life was 31% longer than observed in normal volunteers. Based on increases in bioavailability and half-life, a dose of 60 mg once daily is recommended as the starting dose in patients

with decreased renal function. (See DOSAGE AND ADMINISTRATION).

Hepatic Impairment:
The pharmacokinetics of fexofenadine hydrochloride in patients with hepatic disease did not differ substantially from that observed in healthy patients.

Effect of Gender:
Across several trials, no clinically significant gender-related differences were observed in the pharmacokinetics of fexofenadine hydrochloride.

PHARMACODYNAMICS

Wheal and Flare:
Human histamine skin wheal and flare studies 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.
Histamine skin wheal and flare studies in 7 to 12 year old patients showed that following a single dose of 30 or 60 mg, antihistamine effect was observed at 1 hour and reached a maximum by 3 hours. Greater than 49% inhibition of wheal area, and 74% inhibition of flare area were maintained for 8 hours following the 30 and 60 mg dose.

Effects on QTC:
In dogs (30 mg/kg/orally twice a day), and in rabbits (10 mg/kg, infused intravenously over 1 hour) fexofenadine hydrochloride did not prolong QTC. In dogs, the plasma fexofenadine concentration was approximately 9 times the therapeutic plasma concentrations in adults receiving the maximum recommended daily oral dose. In rabbits, the plasma fexofenadine concentration was approximately 20 times the therapeutic plasma concentration in adults receiving the maximum recommended daily oral dose. No effect was observed on calcium channel current, delayed potassium channel current, or action potential duration in guinea pig myocytes, sodium current in rat neonatal myocytes, or on several delayed rectifier potassium channels cloned from human heart at concentrations up to 1of fexofenadine hydrochloride.
No statistically significant increase in mean QTC interval compared to placebo was observed in 714 seasonal allergic rhinitis patients given fexofenadine hydrochloride capsules in doses of 60 to 240 mg twice daily for two weeks. Pediatric patients from two placebo controlled trials (n=855) treated with up to 60 mg fexofenadine hydrochloride twice daily demonstrated no significant treatment or dose-related increases in QTC. In addition, no statistically significant increase in mean QTC interval compared to placebo was observed in 40 healthy volunteers given fexofenadine hydrochloride as an oral solution at doses up to 400 mg twice daily for 6 days, or in 231 healthy volunteers given fexofenadine hydrochloride 240 mg once daily for 1 year.

CLINICAL STUDIES

Seasonal Allergic Rhinitis:

Adults:
In three, 2-week, multicenter, randomized, double-blind, placebo-controlled trials in patients 12 to 68 years of age with seasonal allergic rhinitis (n=1634), fexofenadine hydrochloride 60 mg twice daily significantly reduced total symptom scores (the sum of the individual scores for sneezing, rhinorrhea, itchy nose/palate/throat, itchy/watery/red eyes) compared to placebo. Statistically significant reductions in symptom scores were observed following the first 60 mg dose, with the effect maintained throughout the 12-hour interval. In these studies, there was no additional reduction in total symptom scores with higher doses of fexofenadine hydrochloride up to 240 mg twice daily.
In one 2-week, multicenter, randomized, double-blind clinical trial in patients 12 to 65 years of age with seasonal allergic rhinitis (n=863), fexofenadine hydrochloride 180 mg once daily significantly reduced total symptom scores (the sum of the individual scores for sneezing, rhinorrhea, itchy nose/palate/throat, itchy/watery/red eyes) compared to placebo. Although the number of patients in some of the subgroups was small, there were no significant differences in the effect of fexofenadine hydrochloride across subgroups of patients defined by gender, age, and race. Onset of action for reduction in total symptom scores, excluding nasal congestion, was observed at 60 minutes compared to placebo following a

single 60 mg fexofenadine hydrochloride dose administered to patients with seasonal allergic rhinitis who were exposed to ragweed pollen in an environmental exposure unit. In one clinical trial conducted with fexofenadine hydrochloride 60 mg capsules, and in one clinical trial conducted with fexofenadine hydrochloride and pseudoephedrine hydrochloride extended release tablets, onset of action was seen within 1 to 3 hours.

Pediatrics:
Two 2-week multicenter, randomized, placebo-controlled, double-blind trials in 877 pediatric patients 6 to 11 years of age with seasonal allergic rhinitis were conducted at doses of 15, 30, and 60 mg twice daily. In one of these two studies, conducted in 411 pediatric patients, all three doses of fexofenadine hydrochloride significantly reduced total symptom scores (the sum of the individual scores for sneezing, rhinorrhea, itchy nose/palate/throat, itchy/watery/red eyes) compared to placebo, however a dose response relationship was not seen. The 60 mg twice daily dose did not provide any additional benefit over the 30 mg twice daily dose. Furthermore, exposure in pediatric patients given 30 mg fexofenadine hydrochloride is comparable to adults given 60 mg (see CLINICAL PHARMACOLOGY).
Additional clinical study information related to safety of fexofenadine in pediatric patients is approved for Aventis Pharmaceuticals'fexofenadine hydrochloride drug products. However, due to Aventis Pharmaceuticals'marketing exclusivity rights, this drug product is not labeled for use in children less than 6 years of age.

Chronic Idiopathic Urticaria:
Two 4-week multicenter, randomized, double-blind, placebo-controlled clinical trials compared four different doses of fexofenadine hydrochloride tablet (20, 60, 120, and 240 mg twice daily) to placebo in patients aged 12 to 70 years with chronic idiopathic urticaria (n=726). Efficacy was demonstrated by a significant reduction in mean pruritus scores (MPS), mean number of wheals (MNW), and mean total symptom scores (MTSS, the sum of the MPS and MNW score). Although all four doses were significantly superior to placebo, symptom reduction was greater and efficacy was maintained over the entire 4-week treatment period with fexofenadine hydrochloride doses of60 mg twice daily. However, no additional benefit of the 120 or 240 mg fexofenadine hydrochloride twice daily dose was seen over the 60 mg twice daily dose in reducing symptom scores. There were no significant differences in the effect of fexofenadine hydrochloride across subgroups of patients defined by gender, age, weight, and race.

INDICATIONS & USAGE
Seasonal Allergic Rhinitis:
Fexofenadine hydrochloride is indicated for the relief of symptoms associated with seasonal allergic rhinitis in adults and children 6 years of age and older. Symptoms treated effectively were sneezing, rhinorrhea, itchy nose/palate/throat, itchy/watery/red eyes.

Chronic Idiopathic Urticaria:
Fexofenadine hydrochloride is indicated for treatment of uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 years of age and older. It significantly reduces pruritus and the number of wheals.

CONTRAINDICATIONS
Fexofenadine hydrochloride is contraindicated in patients with known hypersensitivity to any of its ingredients.

PRECAUTIONS
Drug Interaction with Erythromycin and Ketoconazole:
Fexofenadine hydrochloride has been shown to exhibit minimal (ca. 5%) metabolism. However, co-administration of fexofenadine hydrochloride with ketoconazole and erythromycin led to increased plasma levels of fexofenadine hydrochloride. Fexofenadine hydrochloride had no effect on the pharmacokinetics of erythromycin and ketoconazole. In two separate studies, fexofenadine hydrochloride 120 mg twice daily (two times the recommended twice daily dose) was co-administered with erythromycin 500 mg every 8 hours or ketoconazole 400 mg once daily under steady-state

conditions to normal, healthy volunteers (n=24, each study). No differences in adverse events or QTC interval were observed when patients were administered fexofenadine hydrochloride alone or in combination with erythromycin or ketoconazole. The findings of these studies are summarized in the following table:

Effects on steady-state fexofenadine hydrochloride pharmacokinetics after 7 days of co-administration with fexofenadine hydrochloride 120 mg every 12 hours (two times the recommended twice daily dose) in normal volunteers (n=24)
Concomitant DrugCmaxSS (Peak plasma concentration)AUCSS(0-12h) (Extent of systemic exposure)Erythromycin (500 mg every 8 hrs)+82%+109%Ketoconazole (400 mg once daily)+135%+164%The changes in plasma levels were within the range of plasma levels achieved in adequate and well-controlled clinical trials.
The mechanism of these interactions has been evaluated in in vitro, in situ, and in vivo animal models. These studies indicate that ketoconazole or erythromycin co-administration enhances fexofenadine gastrointestinal absorption. In vivo animal studies also suggest that in addition to increasing absorption, ketoconazole decreases fexofenadine hydrochloride gastrointestinal secretion, while erythromycin may also decrease biliary excretion.

Drug Interactions with Antacids:
Administration of 120 mg of fexofenadine hydrochloride (260 mg capsule) within 15 minutes of an aluminum and magnesium containing antacid (Maaloxdecreased fexofenadine AUC by 41% and Cmax by 43%. Fexofenadine hydrochloride should not be taken closely in time with aluminum and magnesium containing antacids.

CARCINOGENESIS & MUTAGENESIS & IMPAIRMENT OF FERTILITY
The carcinogenic potential and reproductive toxicity of fexofenadine hydrochloride were assessed using terfenadine studies with adequate fexofenadine hydrochloride exposure (based on plasma area-under-the-concentration vs. time [AUC] values). No evidence of carcinogenicity was observed in an 18-month study in mice and in a 24-month study in rats at oral doses up to 150 mg/kg of terfenadine (which led to fexofenadine exposures that were respectively approximately 3 and 5 times the exposure from the maximum recommended daily oral dose of fexofenadine hydrochloride in adults and children).
In in vitro (Bacterial Reverse Mutation, CHO/HGPRT Forward Mutation, and Rat Lymphocyte Chromosomal Aberration assays) and in vivo (Mouse Bone Marrow Micronucleus assay) tests, fexofenadine hydrochloride revealed no evidence of mutagenicity.
In rat fertility studies, dose-related reductions in implants and increases in postimplantation losses were observed at an oral dose of 150 mg/kg of terfenadine (which led to fexofenadine hydrochloride exposures that were approximately 3 times the exposure of the maximum recommended daily oral dose of fexofenadine hydrochloride in adults).

PREGNANCY
Teratogenic Effects:

Category C:
There was no evidence of teratogenicity in rats or rabbits at oral doses of terfenadine up to 300 mg/kg (which led to fexofenadine exposures that were approximately 4 and 31 times, respectively, the exposure from the maximum recommended daily oral dose of fexofenadine in adults).
There are no adequate and well controlled studies in pregnant women. Fexofenadine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic Effects:
Dose-related decreases in pup weight gain and survival were observed in rats exposed to an oral dose of 150 mg/kg of terfenadine (approximately 3 times the maximum recommended daily oral dose of fexofenadine hydrochloride in adults based on comparison of fexofenadine hydrochloride AUCs).

NURSING MOTHERS
There are no adequate and well-controlled studies in women during lactation. Because many drugs are

excreted in human milk, caution should be exercised when fexofenadine hydrochloride is administered to a nursing woman.

PEDIATRIC USE

The recommended dose in patients 6 to 11 years of age is based on cross-study comparison of the pharmacokinetics of fexofenadine hydrochloride in adults and pediatric patients and on the safety profile of fexofenadine hydrochloride in both adult and pediatric patients at doses equal to or higher than the recommended doses.

The safety of fexofenadine hydrochloride tablets at a dose of 30 mg twice daily has been demonstrated in 438 pediatric patients 6 to 11 years of age in two placebo-controlled 2-week seasonal allergic rhinitis trials. The safety of fexofenadine hydrochloride for the treatment of chronic idiopathic urticaria in patients 6 to 11 years of age is based on cross-study comparison of the pharmacokinetics of fexofenadine hydrochloride in adult and pediatric patients and on the safety profile of fexofenadine in both adult and pediatric patients at doses equal to or higher than the recommended dose.

The effectiveness of fexofenadine hydrochloride for the treatment of seasonal allergic rhinitis in patients 6 to 11 years of age was demonstrated in one trial (n=411) in which fexofenadine hydrochloride tablets 30 mg twice daily significantly reduced total symptom scores compared to placebo, along with extrapolation of demonstrated efficacy in patients ages 12 years and above, and the pharmacokinetic comparisons in adults and children. The effectiveness of fexofenadine hydrochloride for the treatment of chronic idiopathic urticaria in patients 6 to 11 years of age is based on an extrapolation of the demonstrated efficacy of fexofenadine hydrochloride in adults with this condition and the likelihood that the disease course, pathophysiology and the drug's effect are substantially similar in children to that of adult patients.

Additional clinical study information related to safety of fexofenadine in pediatric patients is approved for Aventis Pharmaceuticals'fexofenadine hydrochloride drug products. However, due to Aventis Pharmaceuticals'marketing exclusivity rights, this drug product in not labeled for use in children less than 6 years of age.

GERIATRIC USE

Clinical studies of fexofenadine hydrochloride tablets did not include sufficient numbers of subjects aged 65 years and over to determine whether this population responds differently from younger patients. Other reported clinical experience has not identified differences in responses between the geriatric and younger patients. This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and may be useful to monitor renal function. (See CLINICAL PHARMACOLOGY).

ADVERSE REACTIONS

Seasonal Allergic Rhinitis:

Adults:

In placebo-controlled seasonal allergic rhinitis clinical trials in patients 12 years of age and older, which included 2461 patients receiving fexofenadine hydrochloride capsules at doses of 20 mg to 240 mg twice daily, adverse events were similar in fexofenadine hydrochloride and placebo-treated patients. All adverse events that were reported by greater than 1% of patients who received the recommended daily dose of fexofenadine hydrochloride (60 mg capsules twice daily), and that were more common with fexofenadine hydrochloride than placebo, are listed in Table 1.

In a placebo-controlled clinical study in the United States, which included 570 patients aged 12 years and older receiving fexofenadine hydrochloride tablets at doses of 120 or 180 mg once daily, adverse events were similar in fexofenadine hydrochloride and placebo-treated patients. Table 1 also lists adverse experiences that were reported by greater than 2% of patients treated with fexofenadine hydrochloride tablets at doses of 180 mg once daily and that were more common with fexofenadine hydrochloride than placebo.

The incidence of adverse events, including drowsiness, was not dose-related and was similar across subgroups defined by age, gender, and race.

Table 1 Adverse experiences in patients ages 12 years and older reported in placebo-controlled seasonal allergic rhinitis clinical trials in the United States Twice daily dosing with fexofenadine capsules at rates of greater than 1%

Adverse Experience	Fexofenadine 60 mg Twice Daily (n=679)	Placebo Twice Daily (n=671)
Viral Infection (cold, flu)	2.5%	1.5%
Nausea	1.6%	1.5%
Dysmenorrhea	1.5%	0.3%
Drowsiness	1.3%	0.9%
Dyspepsia	1.3%	0.6%
Fatigue	1.3%	0.9%

Once daily dosing with fexofenadine hydrochloride tablets at rates of greater than 2%

Adverse Experience	Fexofenadine 180 mg Once Daily (n=283)	Placebo (n=293)
Headache	10.6%	7.5%
Upper Respiratory Tract Infection	3.2%	3.1%
Back Pain	2.8%	1.4%

The frequency and magnitude of laboratory abnormalities were similar in fexofenadine hydrochloride and placebo-treated patients.

Pediatric:
Table 2 lists adverse experiences in patients aged 6 to 11 years of age which were reported by greater than 2% of patients treated with fexofenadine hydrochloride tablets at a dose of 30 mg twice daily in placebo-controlled seasonal allergic rhinitis studies in the United States and Canada that were more common with fexofenadine hydrochloride than placebo.

Table 2 Adverse experiences reported in placebo-controlled seasonal allergic rhinitis studies in pediatric patients ages 6 to 11 in the United States and Canada at rates of greater than 2%

Adverse Experience	Fexofenadine 30 mg Twice Daily (n=209)	Placebo (n=229)
Headache	7.2%	6.6%
Accidental Injury	2.9%	1.3%
Coughing	3.8%	1.3%
Fever	2.4%	0.9%
Pain	2.4%	0.4%
Otitis Media	2.4%	0.0%
Upper Respiratory Tract Infection	4.3%	1.7%

Additional clinical study information related to safety of fexofenadine in pediatric patients is approved for Aventis Pharmaceuticals'fexofenadine hydrochloride drug products. However, due to Aventis Pharmaceuticals'marketing exclusivity rights, this drug product in not labeled for use in children less than 6 years of age.

Chronic Idiopathic Urticaria:
Adverse events reported by patients 12 years of age and older in placebo-controlled chronic idiopathic urticaria studies were similar to those reported in placebo-controlled seasonal allergic rhinitis studies. In placebo-controlled chronic idiopathic urticaria clinical trials, which included 726 patients 12 years of age and older receiving fexofenadine hydrochloride tablets at doses of 20 to 240 mg twice daily, adverse events were similar in fexofenadine hydrochloride and placebo-treated patients. Table 3 lists adverse experiences in patients aged 12 years and older which were reported by greater than 2% of patients treated with fexofenadine hydrochloride 60 mg tablets twice daily in controlled clinical studies in the United States and Canada and that were more common with fexofenadine hydrochloride than placebo. The safety of fexofenadine hydrochloride in the treatment of chronic idiopathic urticaria in pediatric patients 6 to 11 years of age is based on the safety profile of fexofenadine hydrochloride in adults and adolescent patients at doses equal to or higher than the recommended dose (see Pediatric Use).

Table 3 Adverse experiences reported in patients 12 years and older in placebo-controlled chronic idiopathic urticaria studies in the United States and Canada at rates of greater than 2%

Adverse Experience	Fexofenadine 60 mg Twice Daily (n=186)	Placebo (n=178)
Back Pain	2.2%	1.1%
Sinusitis	2.2%	1.1%
Dizziness	2.2%	0.6%
Drowsiness	2.2%	0.0%

Events that have been reported during controlled clinical trials involving seasonal allergic rhinitis and chronic idiopathic urticaria patients with incidences less than 1% and similar to placebo and have been rarely reported during postmarketing surveillance include: insomnia, nervousness, and sleep disorders or paranoia. In rare cases, rash, urticaria, pruritis, and hypersensitivty reactions with manifestations such as angioedema, chest tightness, dyspnea, flushing and systemic anaphylaxis have been reported.

OVERDOSAGE
Reports of fexofenadine hydrochloride overdose have been infrequent and contain limited information. However, dizziness, drowsiness, and dry mouth have been reported. Single doses of fexofenadine hydrochloride up to 800 mg (six normal volunteers at this dose level), and doses up to 690 mg twice daily for 1 month (three normal volunteers at this dose level) or 240 mg once daily for 1 year (234 normal volunteers at this dose level) were administered without the development of clinically significant adverse events as compared to placebo.
In the event of overdose, consider standard measures to remove any unabsorbed drug. Symptomatic and supportive treatment is recommended.

Hemodialysis did not effectively remove fexofenadine hydrochloride from blood (1.7% removed) following terfenadine administration.
No deaths occurred at oral doses of fexofenadine hydrochloride up to 5000 mg/kg in mice (110 times the maximum recommended daily oral dose in adults and 200 times the maximum recommended daily oral dose in children based on mg/m2) and up to 5000 mg/kg in rats (230 times the maximum recommended daily oral dose in adults and 400 times the maximum recommended daily oral dose in children based on mg/m2). Additionally, no clinical signs of toxicity or gross pathological findings were observed. In dogs, no evidence of toxicity was observed at oral doses up to 2000 mg/kg (300 times the maximum recommended daily oral dose in adults and 530 times the maximum recommended daily oral dose in children based on mg/m2).

DOSAGE & ADMINISTRATION

Seasonal Allergic Rhinitis:

Adults and Children 12 Years and Older:
The recommended dose of fexofenadine hydrochloride tablets is 60 mg twice daily, or 180 mg once daily. A dose of 60 mg once daily is recommended as the starting dose in patients with decreased renal function (see CLINICAL PHARMACOLOGY).

Children 6 to 11 Years:
The recommended dose of fexofenadine hydrochloride tablets is 30 mg twice daily. A dose of 30 mg once daily is recommended as the starting dose in pediatric patients with decreased renal function (see CLINICAL PHARMACOLOGY).

Chronic Idiopathic Urticaria:

Adults and Children 12 Years and Older:
The recommended dose of fexofenadine hydrochloride tablets is 60 mg twice daily. A dose of 60 mg once daily is recommended as the starting dose in patients with decreased renal function (see CLINICAL PHARMACOLOGY).

Children 6 to 11 Years:
The recommended dose of fexofenadine hydrochloride tablets is 30 mg twice daily. A dose of 30 mg once daily is recommended as the starting dose in pediatric patients with decreased renal function (see CLINICAL PHARMACOLOGY).

HOW SUPPLIED

Fexofenadine hydrochloride tablets USP are available as follows:
30 mgpeach, capsule-shaped, film-coated tablets debossed with93on one side and7251on the other side, in bottles of 100.
60 mgpeach, round, film-coated tablets debossed with93on one side and7252on the other side, in bottles of 100 and 500.
180 mgpeach, round, film-coated tablets debossed with93on one side and7253on the other side, in bottles of 100 and 500.

STORAGE AND HANDLING

Store at 20to 25(68to 77[See USP Controlled Room Temperature]. Protect from excessive moisture. Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).

INFORMATION FOR PATIENTS

Provide the following information to patients and parents/caregivers of pediatric patients taking fexofenadine hydrochloride tablets:

- Fexofenadine hydrochloride tablets are prescribed for the relief of symptoms of seasonal

allergic rhinitis or for the relief of symptoms of chronic idiopathic urticaria (hives). Instruct patients to take fexofenadine hydrochloride tablets only as prescribed. Do not exceed the recommended dose. If any untoward effects occur while taking fexofenadine hydrochloride tablets, discontinue use and consult a doctor.

- Patients who are hypersensitive to any of the ingredients should not use these products.
- Patients who are pregnant or nursing should use these products only if the potential benefit justifies the potential risk to the fetus or nursing infant.
- Advise patients and parents/caregivers of pediatric patients to store the medication in a tightly closed container in a cool, dry place, away from small children.
- Advise patients and parents/caregivers not to take fexofenadine hydrochloride tablets with fruit juices.
- Advise patients to take the fexofenadine hydrochloride tablets with water.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL SECTION
DRUG: Fexofenadine Hydrochloride
GENERIC: Fexofenadine Hydrochloride
DOSAGE: TABLET
ADMINSTRATION: ORAL
NDC: 49349-286-02
STRENGTH:60 mg
COLOR: orange
SHAPE: ROUND
SCORE: No score
SIZE: 9 mm
IMPRINT: 30
QTY: 30

FEXOFENADINE HCL

60 MG TAB

QTY:00030

NDC#: 49349-0286-02 **INT:**MD **ID#:**93 7252

EXPIRES: 6/2012

LOT#: 012345

COL: Orange **SHP:** Round

DIST: TEVA PHARMA USA SELLERSVILLE PA 18960

MFG: TEVA PHARMA IND JERUSALEM 91010 ISRAEL

A. Caution Federal law prohibits transfer of this drug to any person other than for whom it was prescribed.

B. Store at a temperature between 15 degree C and 30 degree C (59 degree F and 86 degree F) {see USP}

C. Re-packaged by: RemedyRepack Inc. 655 Kolter Dr., Indiana, PA 15701, 1-724-465-8762

FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG LABEL	**Item Code (Source)**	NDC:49349-286(NDC:0093-7252)
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FEXOFENADINE HYDROCHLORIDE (FEXOFENADINE)	FEXOFENADINE HYDROCHLORIDE	60 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE	
CROSCARMELLOSE SODIUM	
HYPROMELLOSES	
FERROSOFERRIC OXIDE	
FERRIC OXIDE RED	
LACTOSE MONOHYDRATE	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
POLYETHYLENE GLYCOL	

POVIDONE	
TITANIUM DIOXIDE	

Product Characteristics

Color	orange	**Score**	no score
Shape	ROUND (TABLET)	**Size**	9mm
Flavor		**Imprint Code**	93;7252
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49349-286-02	30 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076447	08/22/2011	

Labeler - REMEDYREPACK INC. (829572556)

Revised: 8/2011 REMEDYREPACK INC.