2/4/03

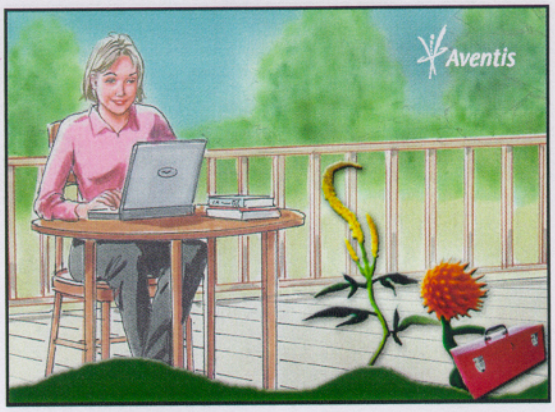
(b)(4)

Allegra 01.10.03
"LAPTOP" :45
1 of 3

IT IS A BEAUTIFUL DAY. IN A MEDIUM SHOT, WE SEE A WOMAN SITTING OUTDOORS AND WORKING INTENTLY ON HER LAPTOP. THERE IS A BOTTLE OF ALLEGRA ON THE TABLE.

ON THE RIGHT HAND SIDE ARE TWO CHARACTERS, POLLEN AND RAGWEED. POLLEN IS THE SHORTER AND MORE ASSERTIVE OF THE TWO. RAGWEED IS TALLER AND HAS A MORE DEMURE THOUGH STILL DEVILISH ATTITUDE. POLLEN IS CARRYING A TOOLBOX WITH HIM.

SUPER: AVENTIS LOGO



RAGWEED: Hey Pollen, what's with the toolbox?

SHE WORKS ON HER LAPTOP.

POLLEN: We got work to do Ragweed. We gotta start her nose running and her eyes itching. Hey, we're allergens. It's what we do.

WE SEE A BOTTLE OF ALLEGRA NEXT TO HER ON THE TABLE.

RAGWEED: See that bottle of Allegra?

POLLEN: Yeah

RAGWEED: It makes this job tough.

POLLEN: Oh really?

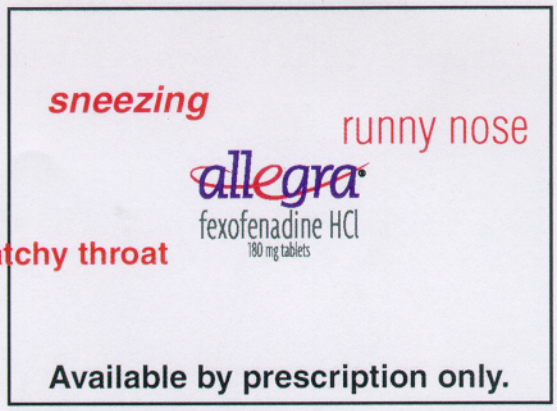
SHE CONTINUES TO WORK.

AVO: Seasonal allergies live to make you miserable.

(b)(4)

CUT TO DEMO.
THE ALLERGY SYMPTOMS MOVE IN TOWARDS THE ALLEGRA LOGO.

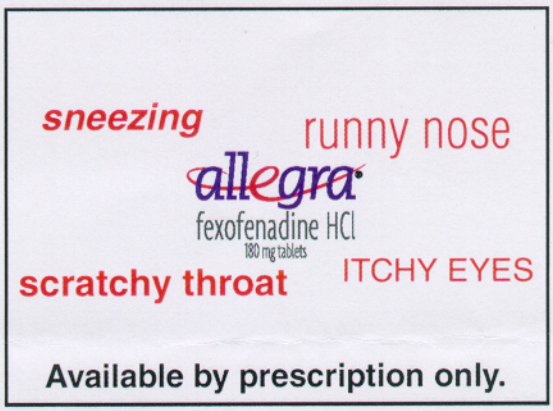
SUPER: AVAILABLE BY PRESCRIPTION ONLY.



But Allegra is specifically designed to block the histamine

ALL THE SYMPTOMS ARE NOW SURROUNDING THE LOGO.

SUPER: AVAILABLE BY PRESCRIPTION ONLY.



that triggers multi-symptom allergic responses.

SYMPTOMS BOUNCE OFF AND AWAY FROM LOGO.

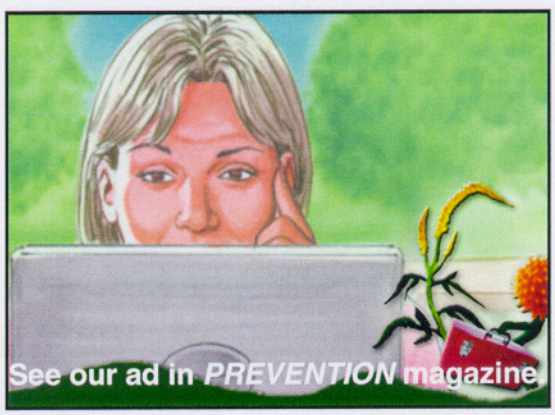
SUPER: AVAILABLE BY PRESCRIPTION ONLY.

Which may be why it's the number one prescription antihistamine.

SHE PAUSES AND REVIEWS HER WORK.

POLLEN PICKS UP HIS TOOLBOX AND STARTS TO LEAVE FRAME WITH RAGWEED.

SUPER: SEE OUR AD IN PREVENTION MAGAZINE.



RAGWEED: Some job you did. Does that look like suffering to you?

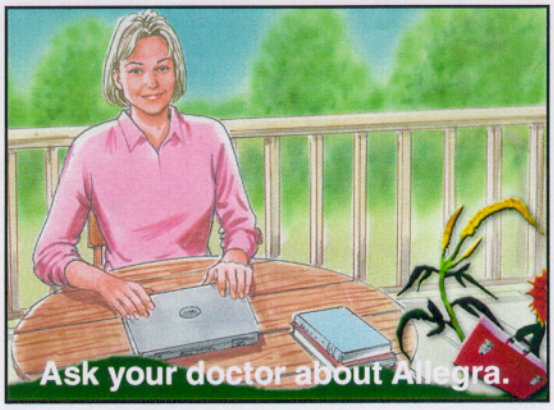
POLLEN: No, actually.

(b)(4)

SHE FINISHES HER WORK, CLOSES HER LAPTOP AND SMILES.

THE CRITTERS CONTINUE OFF THE SCREEN.

SUPER: ASK YOUR DOCTOR ABOUT ALLEGRA.



AVO: Allegra is for people 12 and over. Side effects are low and may include headache, cold or back pain. Ask your doctor about Allegra.

POLLEN: C'mon, let's go find someone we can really hammer.

SUPER:
ALLEGRA. SO MUCH RELIEF FOR SO MANY SYMPTOMS.

ALLEGRA.COM
1-800-ALLEGRA

AVO:
ALLEGRA. SO MUCH RELIEF FOR SO MANY SYMPTOMS.

2/4/03

(b)(4) [redacted]

Allegra 01.15.03
"PLANTING" :30
1 of 3

WE OPEN ON A COUNTRY NURSERY. IT IS A SUNNY DAY AND A WOMAN IS PICKING OUT A VARIETY OF PLANTS. HER EYES ARE RED AND WATERY AS SHE IS SUFFERING FROM AN ALLERGY ATTACK.

SITTING ON THE RIGHT HAND SIDE ARE TWO CHARACTERS, POLLEN AND RAGWEED. POLLEN IS THE SHORTER AND MORE ASSERTIVE OF THE TWO. RAGWEED IS TALLER AND HAS A MORE DEMURE THOUGH STILL DEVILISH ATTITUDE.

SUPER: AVENTIS LOGO

RAGWEED: Don't you love nurseries, Pollen?

AS SHE LOOKS CLOSELY AT THE FLOWERS HER ALLERGIES CONTINUE TO BOTHER HER.

Look at that runny nose and (those) itchy eyes.

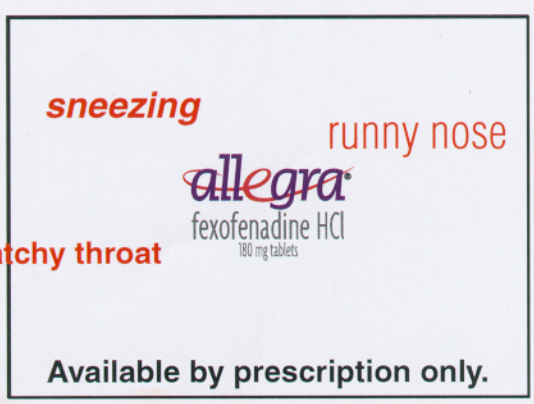
POLLEN: Yeah Ragweed, it doesn't get any better than this.

HER EYES ARE ITCHY AND HER NOSE IS RUNNING. SHE SNEEZES

AVO: Seasonal allergies live to make you miserable.

CUT TO DEMO.
THE ALLERGY SYMPTOMS MOVE IN TOWARDS THE ALLEGRA LOGO.

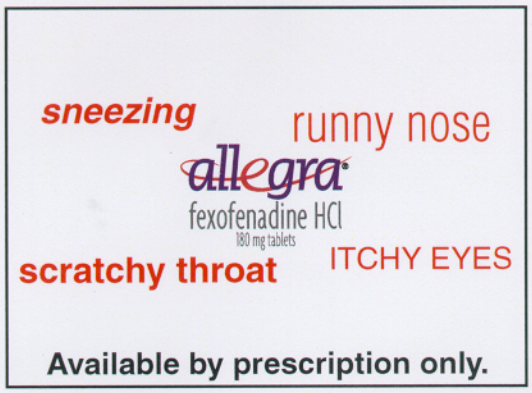
SUPER: AVAILABLE BY PRESCRIPTION ONLY.



But Allegra is specifically designed to block the histamine

(b)(4)

ALL THE SYMPTOMS ARE NOW SURROUNDING THE LOGO.



that triggers so many symptoms.

SYMPTOMS BOUNCE OFF AND AWAY FROM LOGO.

Maybe that's why it's the number one prescription antihistamine.

SHE IS PLANTING HER GARDEN AND NO LONGER SHOWING ALLERGY SYMPTOMS.

POLLEN: Looks like our little garden party's over.

SUPER: SEE OUR AD IN PREVENTION MAGAZINE

RAGWEED: You can thank Allegra for that.

(b)(4) [redacted]

SHE STANDS BACK AND ADMIRES HER WORK.

RAGWEED AND POLLEN EXIT THE FRAME.

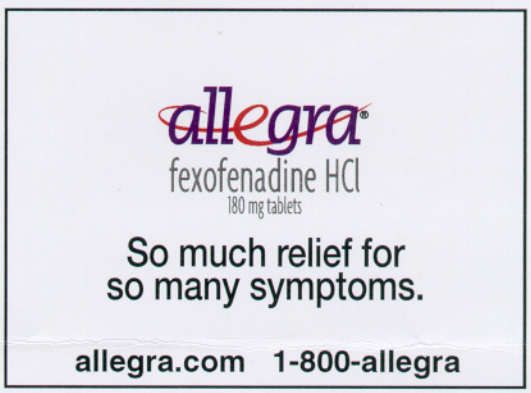
SUPER: ASK YOUR DOCTOR ABOUT ALLEGRA.

AVO: For people 12 and over.
Side effects are low and may include headache, cold or back pain.
Ask your doctor about Allegra.

POLLEN: Allegra. Schmallegra.

SUPER:
ALLEGRA. SO MUCH RELIEF FOR SO MANY SYMPTOMS.

ALLEGRA.COM
1-800-ALLEGRA



AVO:
ALLEGRA. SO MUCH RELIEF FOR SO MANY SYMPTOMS.

Now it's easier and more convenient than ever to save on your Allegra prescriptions.

Here's how Allegra Extras Plus can work for you!

1. Place the attached Rebate Certificates in the enclosed holder for safe-keeping.
2. Visit your doctor and get an Allegra prescription. Allegra comes in several strengths to match a variety of symptoms and needs.
3. Get up to $15 when you fill your Allegra prescription. See the back of your Rebate Certificates for details. Some restrictions may apply.*
4. Send in your first Rebate Certificate and we'll send your choice of extras, such as an umbrella, a gardening kit or a travel coffee mug.
5. Mail your third Rebate Certificate by July 31, 2003 and we'll send you this backpack cooler!

FREE

AFTER THREE REBATES**

The one you'll stay with

Allegra 180 mg tablets give seasonal allergy sufferers the convenient, 24-hour relief they're looking for. In fact, results from a recent independent survey indicate that once people try Allegra 180 mg, they tend to stay with Allegra 180 mg – more than with any other brand of prescription antihistamine for seasonal allergy relief.†

Side effects with Allegra 180 mg are low and may include headache, cold or back pain for people 12 and older.

Remember, the attached Rebate Certificates are time sensitive. So what are you waiting for? Use your Certificates right away and save!

Sincerely,

Jamie Snyder
Customer Service Representative

P.S. If you have a child who suffers from seasonal allergies, use the enclosed postage-free card to order a FREE Allergy Kid's Kit. It makes learning to manage seasonal allergies fun! Side effects with Allegra 30 mg are low and may include headache, cold, coughing and accidental injury in people 6-11 years old.

Please see additional important information enclosed.

* When you purchase Allegra and send in Rebate Certificate with a pharmacy receipt. Federal and state insurance beneficiaries excluded. Not available in MN, MA, MI, MO and RI if any insurer or third party payer reimburses you for any part of the prescription price. See Redemption Certificate for details and other restrictions.

**After three Rebate Certificates are redeemed by July 31, 2003, you will receive the backpack cooler.

† Source: NDC-Retail Pharmacy Database

Aventis

Sometimes it seems your seasonal allergies want to make you miserable in as many ways as they can. That's when you need the multi-symptom relief of Allegra. Allegra is specifically designed to block the histamine that triggers allergic responses like runny nose, itchy eyes and scratchy throat. Which may be one reason it's the number one prescription antihistamine. Allegra is for people 12 and older. Side effects are low and may include headache, cold or back pain. Talk to your doctor about Allegra.

Allegra. So Much Relief for So Many Symptoms.

For more information call 1-800-allegra. Join the extras program @ allegra.com.
Please see additional important information on next page.

Aventis

Brief Summary of Prescribing Information as of November 2000

ALLEGRA®

(fexofenadine hydrochloride)

Capsules and Tablets

INDICATIONS AND USAGE

Seasonal Allergic Rhinitis

ALLEGRA 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

ALLEGRA 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

ALLEGRA 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 QT_c 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 Drug	$C_{max ss}$ *(Peak plasma concentration)*	$AUC_{ss(0-12h)}$ *(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 (2 x 60 mg capsule) within 15 minutes of an aluminum and magnesium containing antacid (Maalox®) decreased fexofenadine AUC by 41% and C_{max} by 43%. ALLEGRA 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 ALLEGRA 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 ALLEGRA 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 ALLEGRA 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 ALLEGRA 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 ALLEGRA for the treatment of seasonal allergic rhinitis in patients 6 to 11 years of age was demonstrated in one trial (n=411) in which ALLEGRA 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 ALLEGRA 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 ALLEGRA 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.

The safety and effectiveness of ALLEGRA in pediatric patients under 6 years of age have not been established.

Geriatric Use

Clinical studies of ALLEGRA tablets and capsules 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	2.8%	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%

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=166)*	*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 paroniria. In rare cases, rash, urticaria, pruritus and hypersensitivity 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).

Prescribing Information as of November 2000

Aventis Pharmaceuticals Inc.
Kansas City, MO 64137 USA
US Patents 4,254,129; 5,375,693; 5,578,610
www.allegra.com
allb1100Aa ALG-JA-6368-1

Aventis

Aventis Pharmaceuticals Bridgewater, NJ 08807

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