

ALLERGY RELIEF- fexofenadine hcl tablet, coated
P & L Development, LLC

DRUG FACTS

Active ingredient (in each film-coated tablet)

Fexofenadine HCl USP 180 mg

Purpose

Antihistamine

Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- itchy, watery eyes
- sneezing
- itching of the nose or throat

Warnings

Do not use

if you have ever had an allergic reaction to this product or any of its ingredients.

Ask a doctor before use if you have

kidney disease. Your doctor should determine if you need a different dose.

When using this product

- do not take more than directed
- do not take at the same time as aluminum or magnesium antacids
- do not take with fruit juices (see Directions)

Stop use and ask a doctor if

an allergic reaction to this product occurs. Seek medical help right away.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

adults and children 12 years of age and over	take one 180 mg tablet with water once a day; do not take more than 1 tablet in 24 hours
children under 12 years of age	do not use
adults 65 years of age and older	ask a doctor
consumers with kidney disease	ask a doctor

Other information

- **each tablet contains:** sodium 8 mg
- store between 20-25°C (68-77°F)
- protect from excessive moisture
- this product meets the requirements of USP Dissolution Test 2

Inactive ingredients

anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, lactose monohydrate, pregelatinized starch (maize), stearic acid, opadry pink 03B84893 containing hypromellose, polyethylene glycol, red iron oxide, titanium dioxide, and yellow iron oxide

Questions or comments?

call **1-877-753-3935 Monday- Friday 9AM- 5PM EST**

Principal Display Panel

allergy relief

Fexofenadine HCl 180 mg

antihistamine

- for indoor and outdoor allergies
- non-drowsy
- original prescription strength

Coated Caplets**

(**Capsule-shaped tablets)

*Compare to the active ingredient in Allegra® Allergy 24 Hour

*This product is not manufactured or distributed by Chattem Inc., distributor of Allegra® Allergy 24 hour.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS

BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by: **PL Developments**

200 Hicks Street Westbury, NY 11590

Product Label

<p>Drug Facts (continued)</p> <p>Other information</p> <ul style="list-style-type: none"> ■ each tablet contains: sodium 8 mg ■ store between 20-25°C (68-77°F) ■ protect from excessive moisture ■ this product meets the requirements of USP Dissolution Test 2 <p>Inactive ingredients anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, lactose monohydrate, polyethylene glycol, pregelatinized starch (maize), red iron oxide, stearic acid, titanium dioxide, and yellow iron oxide</p> <p>Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST</p>	 <p>allergy relief</p> <p>fexofenadine HCl 180 mg antihistamine</p> <p>150 Coated Caplets** (**Capsule-shaped tablets)</p>	 <p>allergy relief</p> <p>fexofenadine HCl 180 mg antihistamine</p> <ul style="list-style-type: none"> • for indoor & outdoor allergies • non-drowsy • original prescription strength <p>150 Coated Caplets** (**Capsule-shaped tablets)</p> <p>*Compare to the active ingredient in Allegra® Allergy 24 Hour</p>	<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active ingredient (in each film-coated tablet)</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Fexofenadine HCl USP 180 mg.....</td> <td>Antihistamine</td> </tr> </tbody> </table> <p>Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: <ul style="list-style-type: none"> ■ runny nose ■ itchy, watery eyes ■ sneezing ■ itching of the nose or throat </p> <p>Warnings Do not use if you have ever had an allergic reaction to this product or any of its ingredients. Ask a doctor before use if you have kidney disease. Your doctor should determine if you need a different dose. When using this product <ul style="list-style-type: none"> ■ do not take more than directed ■ do not take at the same time as aluminum or magnesium antacids ■ do not take with fruit juices (see Directions) Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away. If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. </p> <p>Directions</p> <table border="1"> <tbody> <tr> <td>adults and children 12 years of age and over</td> <td>take one 180 mg tablet with water once a day; do not take more than 1 tablet in 24 hours</td> </tr> <tr> <td>children under 12 years of age</td> <td>do not use</td> </tr> <tr> <td>adults 65 years of age and older</td> <td>ask a doctor</td> </tr> <tr> <td>consumers with kidney disease</td> <td>ask a doctor</td> </tr> </tbody> </table>	Active ingredient (in each film-coated tablet)	Purpose	Fexofenadine HCl USP 180 mg.....	Antihistamine	adults and children 12 years of age and over	take one 180 mg tablet with water once a day; do not take more than 1 tablet in 24 hours	children under 12 years of age	do not use	adults 65 years of age and older	ask a doctor	consumers with kidney disease	ask a doctor
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<p>Distributed by: PL Developments 200 Hicks Street, Westbury, NY 11590</p>															
 <p>X003CA941R</p> <p>Wellness Basics - Allergy...Indoor & Outdoor Allergies New</p> <p>PLD-8416B FC008864 Product of India</p> <p>Lot No.: Exp. Date:</p>															

WELLNESS BASICS Allergy Relief

ALLERGY RELIEF

fexofenadine hcl tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-505
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
FEXOFENADINE HYDROCHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)		FEXOFENADINE HYDROCHLORIDE	180 mg	
Inactive Ingredients				
Ingredient Name			Strength	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)				
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)				
STARCH, CORN (UNII: O8232NY3SJ)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
Product Characteristics				
Color	white	Score	no score	
Shape	CAPSULE	Size	17mm	
Flavor		Imprint Code	SG;202	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-505-30	1 in 1 BOX	01/31/2018	
1		30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:59726-505-15	1 in 1 BOX	01/31/2018	
2		150 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA204507	01/31/2018		

Labeler - P & L Development, LLC (800014821)