

ALLERGY RELIEF- fexofenadine hcl tablet
Allwell Health Inc

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 (1-

800-222-1222).

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, hypromellose, lactose monohydrate, polyethylene glycol, pregelatinized starch (maize), red iron oxide, stearic acid, 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 USP 180 mg

antihistamine

24 hour relief of

- runny nose
- sneezing
- itchy, watery eyes
- itchy nose or throat

non-drowsy

coated caplets**

(**capsule-shaped tablets)

**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS
BROKEN OR MISSING.**

distributed by:

AllWell Health, Inc.

Princeton, NJ 08540

getallwell.com

Product Label

NDC 80539-504-30



allergy relief

fexofenadine HCl 180 mg

antihistamine

24 hour relief of

- runny nose
- sneezing
- itchy, watery eyes
- itchy nose or throat

non-drowsy

30 coated caplets** / actual size

(**capsule-shaped tablets)



distributed by:
AllWell Health, Inc.
Princeton, NJ 08540
getallwell.com

Lot No.:
Exp. Date:

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

1 BOTTLE INSIDE

PLD-B416B FC007695

Questions or comments? Call 877-753-3939 Monday-Friday 9AM-5PM EST	
Inactive ingredients	anhydrous lactose, croscarmellose sodium, hypromellose, lactose monohydrate, polyethylene glycol, pregelatinized starch (maize), red iron oxide, stearic acid, titanium dioxide, and yellow iron oxide.
Other information	<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
Directions	<p>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.</p> <p>children under 12 years of age: do not use.</p> <p>adults 65 years of age and older: ask a doctor.</p> <p>consumers with kidney disease: ask a doctor.</p>
Warnings	<p>Do not use if you have ever had an allergic reaction to this product or any of its ingredients.</p> <p>Ask a doctor before use if you have kidney disease. Your doctor should determine if you need a different dose.</p> <p>When using this product:</p> <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) <p>Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).</p>



ALLWELL Allergy Relief

ALLERGY RELIEF

fexofenadine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80539-504
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	pink	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	SG;202
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80539-504-30	1 in 1 BOX	01/29/2021	

1	30 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	01/29/2021	

Labeler - Allwell Health Inc (117644800)

Revised: 9/2022

Allwell Health Inc