ALLERGY RELIEF- fexofenadine hcl tablet Allwell Health Inc

DRUG FACTS

Active ingredient (in each film-coated tablet)

Fexofenadine HCI 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-

Directions

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

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 HCI 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





allergy relief

fexofenadine HCI 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)

Date Lot No.:

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

1 BOTTLE INSIDE

PLD-84168 FC007695

Questions or comments?

Cal 877-763-3936 Monday-Friday 9AM- 5PM EST

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Control Center right away (1-600-222-1222). If pregnant or breast-feeding, sak a health professional before use. Keep out of reach or childran, in case of overdose, get medical help or contact a Poison Control Compact data way or action 2002-1903.

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ALLWELL Allergy Relief

ALLERGY RELIEF

fexofenadine hcl tablet

Product Information

Item Code (Source) Product Type HUMAN OTC DRUG NDC:80539-504

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength FEXOFENADINE HYDROCHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE -**FEXOFENADINE**

UNII:E6582LOH6V)

HYDROCHLORIDE

180 mg

Inactive Ingredients

Ingredient Name	Strength

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)

CROSCARMELLOSE SODIUM (UNII: M280L1HH48)

HYPROMELLOSES (UNII: 3NXW29V3WO) FERRIC OXIDE RED (UNII: 1K09F3G675) FERRIC OXIDE YELLOW (UNII: EX43802MRT) LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3M/Q0SDW1A)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)

STARCH, CORN (UNII: O8232NY3S)) STEARIC ACID (UNII: 4ELV7Z65AP)

Product Characteristics

Color	pink	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	SG;202
Contains			

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# Item Code Package Description		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: 7/2023 Allwell Health Inc