FEXOFENADINE HYDROCHLORIDE- fexofenadine hydrochloride tablet CVS PHARMACY, INC

Fexofenadine Hydrochloride Tablets, USP 180 mg

Drug Facts

Active ingredient (in each 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

- safety sealed: do not use if carton is opened or if inner safety seal is torn or missing
- store between 20° to 25°C (68° to 77°F)
- protect from excessive moisture

Inactive ingredients

croscarmellose sodium, hypromellose, iron oxide red, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized maize starch, titanium dioxide

Questions or comments?

Call toll-free weekdays 8:30 AM to 5 PM EST **at 1-800-818-4555**.

Distributed by: CVS Pharmacy, Inc.One CVS Drive

Woonsocket, RI 02895

PRINCIPAL DISPLAY PANEL - 180 mg Tablet Bottle Carton

CVS Health®

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

NDC 51316-800-70

Allergy Relief

FEXOFENADINE HYDROCHLORIDE TABLETS, USP 180 mg
Antihistamine

INDOOR/OUTDOOR ALLERGY RELIEF

24 HOUR

Sneezing

- Runny nose
- Itchy, watery eyesItchy nose or throat

Non-Drowsy

Package Contains One Bottle

70 TABLETS

Actual Size





5237165

Drug Facts (continued)
Directions





FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51316-800	
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		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)			
STARCH, CORN (UNII: O8232NY3SJ)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	

Product Characteristics				
Color	PINK	Score	no score	
Shape	OVAL	Size	17mm	
Flavor		Imprint Code	545	
Contains				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:51316- 800-90	1 in 1 CARTON	09/20/2022			
1		90 in 1 BOTTLE; Type 0: Not a Combination Product				
2	NDC:51316- 800-70	1 in 1 CARTON	09/20/2022			
2		70 in 1 BOTTLE; Type 0: Not a Combination Product				
3	NDC:51316- 800-45	1 in 1 CARTON	09/20/2022			
3		45 in 1 BOTTLE; Type 0: Not a Combination Product				
4	NDC:51316- 800-30	1 in 1 CARTON	09/20/2022			
4		30 in 1 BOTTLE; Type 0: Not a Combination Product				
5	NDC:51316- 800-15	1 in 1 CARTON	09/20/2022			
5		15 in 1 BLISTER PACK; Type 0: Not a Combination Product				
6	NDC:51316- 800-08	1 in 1 CARTON	09/20/2022			
6		180 in 1 BOTTLE; Type 0: Not a Combination Product				

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA091567	09/20/2022	

Labeler - CVS PHARMACY, INC (062312574)

Establishment			
Name	Address	ID/FEI	Business Operations

CVS PHARMACY, INC Revised: 2/2023