# FEXOFENADINE HYDROCHLORIDE- fexofenadine hydrochloride tablet CVS PHARMACY, INC

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### 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\*

NDC 51316-800-70

Non-Drowsy

Allergy Relief

FEXOFENADINE HYDROCHLORIDE TABLETS, USP 180 mg Antihistamine

24 HOUR

INDOOR/OUTDOOR

### ALLERGY RELIEF

- Sneezing
- Runny noseItchy, watery eyes
- Itchy nose or throat

Package Contains One Bottle

**70 TABLETS** 

**Actual Size** 





HYDROCHLORIDE TABLETS, USP 180 mg **Antihistamine** 







Compare to the active ingredient in Allegra® Allergy\* NDC 51316-800-70

**Non-Drowsy** 

# Allergy

**FEXOFENADINE HYDROCHLORIDE** TABLETS, USP 180 mg Antihistamine

DO NOT USE IF INNER SAFETY SEAL IMPRINTED WITH "SEALED FOR YOUR PROTECTION" IS TORN OR MISSING.

\*This product is not manufactured or distributed by Chattem, Inc. (part of the Sanofi Group), distributor of Allegra\* Allergy. Allegra\* is a registered trademark of Aventisub, LLC.

Non-Drowsy

# ergy Relief

FEXOFENADINE HYDROCHLORIDE TABLETS, USP 180 mg

Antihistamine

### INDOOR/OUTDOOR **ALLERGY RELIEF**

- Sneezing
- Runny nose
- Itchy, watery eyes
- · Itchy nose or throat

Package Contains One Bottle

**70** TABLETS



Actual Size



Unvarnish Area: 90x50 mm

ISS. 04/2024

### **Drug Facts**

### Active ingredient (in each tablet)

Purpose

Fexofenadine HCI, USP 180 mg.....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).

### Drug Facts (continued)

### Directions

take one 180 mg tablet with water once a day; do not take more than 1 tablet in 24 hours
do not use
ask a doctor
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

croscarme ose sodium, hypromellose, iron oxide red, iron oxide yellow, magnesium stearate, microcrysta ine ce ulose, polyethylene glycol, pregelatinized maize starch, titanium dioxide

#### Questions or comments?

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Made in India V-14192

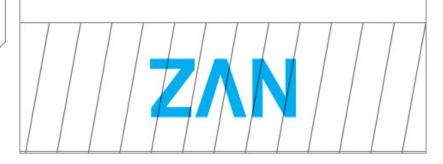


PAPER PLASTIC BOX BOTTLE

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DNH/DRUGS/NH/138



### **FEXOFENADINE HYDROCHLORIDE**

fexofenadine hydrochloride tablet

Product Type HUMAN OTC DRUG Item Code (Source) NDC:51316-800

**Route of Administration** Oral

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	Strength
	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 Marketing Start Marketing End Category Citation Date Date					
ANDA	ANDA091567	09/20/2022			

## Labeler - CVS PHARMACY, INC (062312574)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Sun Pharmaceutical Industries Limited		650445203	MANUFACTURE(51316-800)	

Revised: 5/2024 CVS PHARMACY, INC