

**FEXOFENADINE HYDROCHLORIDE- fexofenadine hydrochloride tablet, film coated  
Granules USA, Inc**

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**Original Prescription Strength  
ALLERGY  
Fexofenadine Hydrochloride  
Tablets USP, 180 mg  
Antihistamine  
24 Hour Relief of**

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

**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 and 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 180mg 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**

- store between 20°and 25°C (68°and 77°F)
- protect from excessive moisture
- **each tablet contains:** sodium 8.2 mg
- this product meets the requirements of USP Dissolution Test 2
- **Tamper Evident:** Do not use if imprinted inner safety seal is torn or missing

## **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 1-877-770-3183 Mon-Fri 9:00 AM to 4:30 PM EST

**JOB INFORMATION**

**CUSTOMER:** GRANULES  
**MASTER #:** J77200AM  
**EP# #:** 1009034  
**DIMENSIONS:** 1.75 X 1.75 X 3.375

**COLORS USED:**  
 Cyan  
 Magenta  
 Yellow  
 Black

**JOB HISTORY:**  
 Original: BM  
 New #1: 300  
 New #2: 300  
 New #3: 300

**ATTENTION:**  
 All content in **YELLOW** color does not print.  
 This includes center marks.

**MPS**  
 South Plainfield, NJ 07080

Please enable overprint preview in Acrobat.  
 When viewed correctly you should not see the "X" in this box.

**PDF/X overprint**



# FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69848-002
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
FEXO FENADINE HYDRO CHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	180 mg

Inactive Ingredients	
Ingredient Name	Strength

CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	pink	<b>Score</b>	2 pieces
<b>Shape</b>	OVAL (Capsule shaped, biconvex film coated tablets)	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	SG;202
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69848-002-32	32 in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204507	04/13/2018	

**Labeler** - Granules USA, Inc (137098864)