# FEXOFENADINE HYDROCHLORIDE- fexofenadine hydrochloride tablet, film coated Big Lots Stores, Inc.

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Original Prescription Strength NON-DROWSY Allergy Relief Fexofenadine Hydrochloride Tablets, USP 180mg/Antihis tamine Indoor & Outdoor Allergies

# **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

## **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.

#### **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

# **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?

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



fexofenadine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50594-769
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>FEXO FENADINE HYDRO CHLO RIDE</b> (UNII: 2S068B75ZU) (FEXOFENADINE - UNII: E6582LOH6 V)	FEXOFENADINE HYDROCHLORIDE	180 mg	

Inactive Ingredients		
Ingredient Name	Strength	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)		

Product Characteristics			
Color	pink	Score	no score
Shape	OVAL (Capsule Shaped Tablets)	Size	17mm
Flavor		Imprint Code	SG;202
Contains			

l	Packaging			
l	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
ı	1 NDC:50594-769-03	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/15/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204507	10/15/2018	

Revised: 1/2021 Big Lots Stores, Inc.