# FEXOFENADINE HCL- fexofenadine hcl tablet QUALITY CHOICE (Chain Drug Marketing Association)

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#### **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.

#### **Directions**

	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	do not use
age	
adults 65 years of age and older	ask a doctor
	ask a doctor
disease	ask a doctor

#### 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, lactose monohydrate, pregelatinized starch (maize), stearic acid, opadry pink 03B84893 containing hypromellose, polyethylene glycol, red iron oxide, titanium dioxide, and yellow iron oxide

### Questions or comments?

call 1-248-449-9300 Monday- Friday 9AM- 5PM EST

## **Principal Display Panel**

†Compare to the active ingredient in Allegra® Allergy 24 hour\*

ORIGINAL PRESCRIPTION STRENGTH

Fexofenadine hydrochloride

tablets USP, 180 mg / Antihistamine

Indoor and outdoor allergies

Non-Drowsy

24 Hour Relief of:

sneezing

runny nose

itchy, watery eyes

itchy nose or throat

**Tablets** 

†This product is not manufactured or distributed by Chattem Inc., distributor of Allegra® Allergy 24 hour

# KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

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

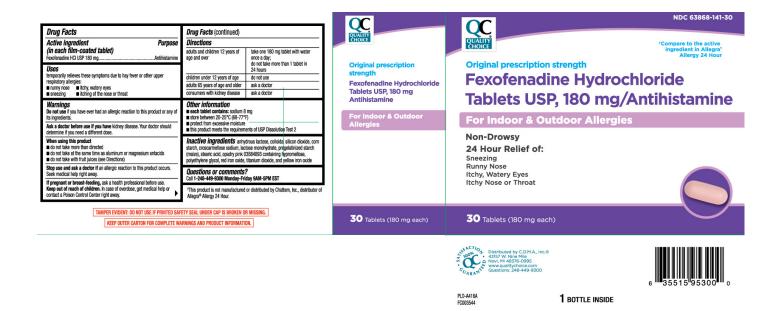
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Novi, MI 48376-0995

www.qualitychoice.com

#### **Product Label**



#### Quality Choice Fexofenadine Hydrochloride Tablets USP, 180 mg

Lot No.:



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	
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: 3WJQ0SDW1A)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)		
STARCH, CORN (UNII: O8232NY3SJ)		
STEARIC ACID (UNII: 4ELV7Z65AP)		

Product Characteristics				
Color	white	Score	no score	
Shape	CAPSULE	Size	17mm	
Flavor		Imprint Code	SG;202	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:63868- 141-30	1 in 1 BOX	03/31/2016	03/31/2025	
1		30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			

Marketing I	Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA079112	03/31/2016	03/31/2025	

Labeler - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)