# FEXOFENADINE HYDROCHLORIDE- fexofenadine hydrochloride tablet Strategic Sourcing Services, LLC

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#### Fexofenadine HCI Tablets USP

## Active ingredient (in each 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 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 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 printed foil inner seal on bottle is torn or missing
- store between 20° and 25°C (68° and 77°F)
- protect from excessive moisture
- this product meets the requirements of USP Dissolution Test 4

## **Inactive ingredients**

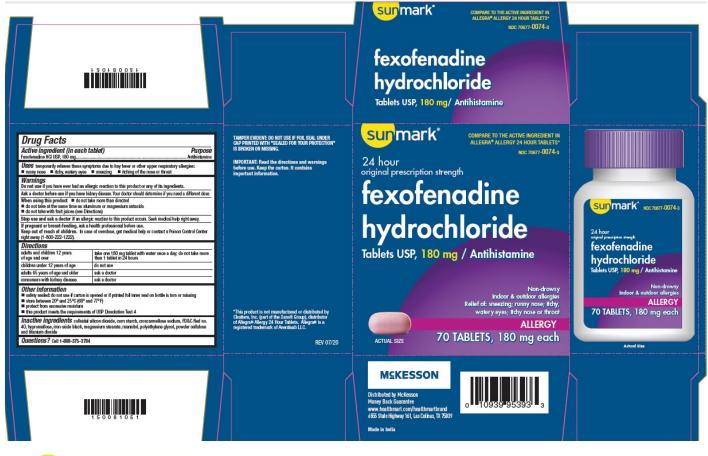
colloidal silicon dioxide, corn starch, croscarmellose sodium, FD&C Red no. 40, hypromellose, iron oxide black, magnesium stearate, mannitol, polyethylene glycol, powder cellulose and titantium dioxide

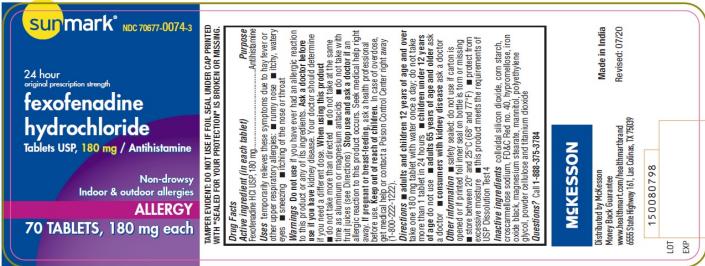
#### **Questions?**

call **1-888-375-3784** 

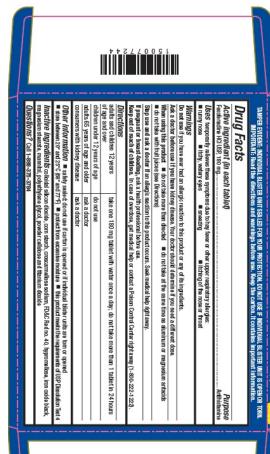
#### Carton Label

70ct Container and Container Carton labels





#### Carton



COMPARE TO THE ACTIVE INGREDIBLY IN ALLEGRAD

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COMPARE TO THE ACTIVE INGREDIENT IN ALLEGRA® ALLERGY 24 HOUR TABLETS\* NDC 70677-0074-1



15 TABLETS, 180 mg each ALLERGY

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101

Non-drow sy Indoor & outdoor dlergies Relief of sneeping rumy nose iddy watery eyes itdy nose or throat Tablets USP, 180 mg / Antihistamine

ACTUAL SIZE

nydrochloride rexotenadine

24 hour

Tablets USP, 180 mg/ Antihistamine

sunmark\*

hydrochloride

fexofenadine

sunmark

original prescription strength

"This product is not manufactured or distributed by Chattem, Inc. (part of the Sanofi Group), distributor of Allegrae Allergy 24 Hour Tablets. Allegrae is a registered trademark of Aventisub LLC.

Revised: 06/19





#### **Container Label**



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 Drug Facts (continued)
Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away, if pregnant or 40, hypromellose, iron oxide black, magnesium stearate, mannitol, polyethylene glycol, powder cellulose on bottle is torn or missing ■ store between 20° and 25°C (68° and 77°F) ■ protect from croscarmellose sodium, FD&C Red no. sealed: do not use if carton was opened or if printed foil inner seal consumers with kidney disease ask a doctor silicon dioxide, corn starch product meets the requirements of USP Dissolution Test 4 excessive moisture ■ this Other information ■ safety older ask a doctor contact a Poison Control Center of reach of children. In case of overdose, get medical help or Questions? Call 1-888-375-3784 and titanium dioxide. Inactive ingredients colloidal right away. professional before use. **Keep ou**i breast-feeding, ask a health

## **FEXOFENADINE HYDROCHLORIDE**

fexofenadine hydrochloride tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70677-0074(NDC:55111-784)	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	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)		
magnesium stearate (UNII: 70097M6I30)		
mannitol (UNII: 3OWL53L36A)		
POWDERED CELLULOSE (UNII: SMD1X3XO9M)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)		
FERROSOFERRIC OXIDE (UNII: XM0M87F357)		
polyethylene glycol 400 (UNII: B697894SGQ)		

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

STARCH, CORN (UNII: 08232NY3SJ)

Product Characteristics			
Color	PINK	Score	no score
Shape	OVAL	Size	7mm
Flavor		Imprint Code	194;R
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:70677- 0074-2	1 in 1 CARTON	09/09/2019		
1		30 in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:70677- 0074-1	3 in 1 CARTON	09/09/2019		
2		5 in 1 BLISTER PACK; Type 0: Not a Combination Product			
3	NDC:70677- 0074-3	70 in 1 CARTON	08/06/2020		
3		70 in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076502	09/09/2019	

## **Labeler -** Strategic Sourcing Services, LLC (116956644)

Revised: 8/2020 Strategic Sourcing Services, LLC