FEXOFENADINE HYDROCHLORIDE - fexofenadine hydrochloride tablet, film coated
Ahold U.S.A., Inc

Active ingredient(in each tablet)

Fexofenadine HCl USP, 180 mg

Purpose

Antihistamine

Uses

temporarily relieves these symptoms due to hay fever or other upper resporatory 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 aluminium 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 and light

Inactive ingredients

anhydrous lactose, colloidal silicon dioxide, corn starch,croscarmellose sodium, hypromellose, lactose monohydrate, polyethylene glycol 400, pregelatinized corn starch, red iron oxide, steric acid, titanium dioxide, and yellow iron oxide,

Questions or comments?

call 1-855-274-4122

Principal Display Panel (180 mg 15 ct)

NDC 60000-409-53

***Compare to Active Ingredient in 24 Hour Allegra®**
Original Prescription Strength Non-Drowsy
Fexofenadine Hydrochloride Tablets USP, 180 mg antihistamine
24 hour relief of Indoor & Outdoor Allergies:
Sneezing
Runny nose
Itchy, Watery Eyes

Itchy Nose or Throat

Principal Display Panel (180 mg 30 ct)

NDC 60000-409-30

***Compare to Active Ingredient in 24 Hour Allegra®**
Original Prescription Strength Non-Drowsy
Fexofenadine Hydrochloride Tablets USP, 180 mg antihistamine
24 hour relief of Indoor & Outdoor Allergies:
Sneezing
Runny nose
Itchy, Watery Eyes
Itchy Nose or Throat

Principal Display Panel (180 mg 45 ct)

NDC 60000-409-45

***Compare to Active Ingredient in 24 Hour Allegra®**
Original Prescription Strength Non-Drowsy
Fexofenadine Hydrochloride Tablets USP, 180 mg antihistamine
24 hour relief of Indoor & Outdoor Allergies:
Sneezing
Runny nose
Itchy, Watery Eyes
Itchy Nose or Throat

Principal Display Panel (180 mg 45 ct+ 50% bonus)

NDC 60000-409-48

***Compare to Active Ingredient in 24 Hour Allegra®**
Original Prescription Strength Non-Drowsy
Fexofenadine Hydrochloride Tablets USP, 180 mg antihistamine
24 hour relief of Indoor & Outdoor Allergies:
Sneezing
Runny nose
Itchy, Watery Eyes
Itchy Nose or Throat

FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:60000-409
Route of Administration	ORAL		

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**
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	ORANGE (Peach)	**Score**	no score
Shape	CAPSULE (Bevel Edge, Biconvex)	**Size**	17mm
Flavor		**Imprint Code**	E;44
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60000-409-48	1 in 1 CARTON	01/15/2015	
1		45 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:60000-409-30	1 in 1 CARTON	01/15/2015	
2		30 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:60000-409-53	1 in 1 CARTON	01/15/2015	
3		15 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:60000-409-45	1 in 1 CARTON	01/15/2015	
4		45 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	ANDA202039	01/15/2015	

Labeler - Ahold U.S.A., Inc (188910863)

Establishment

Name	Address	ID/FEI	Business Operations
Aurolife Pharma, LLC		829084461	MANUFACTURE(60000-409)

Revised: 9/2019 Ahold U.S.A., Inc