FEXOFENADINE HYDROCHLORIDE- fexofenadine hydrochloride tablet Sam's West Inc.

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

	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**

Card



Container Label



FEXOFENADINE HYDROCHLORIDE fexofenadine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68196-107(NDC:55111-784)
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Fexofenadine Hydrochloride (UNII: 2S068B75ZU) (FEXOFENADINE -	Fexofenadine	100 ma	

Inactive Ingredients				
Ingredient Name	Strength			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
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: O8232NY3SJ)				

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:68196-107- 15	1 in 1 CARTON	05/09/2017		
1		150 in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:68196-107- 50	150 in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2023		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076502	05/09/2017	

Labeler - Sam's West Inc. (051957769)

Revised: 10/2019 Sam's West Inc.