FEXOFENADINE HYDROCHLORIDE- fexofenadine hydrochloride tablet, film coated SPIRIT PHARMACEUTICALS LLC

Fexofenadine Hydrochloride Tablets, 180 mg

Drug Facts

Active ingredient (in each caplet)
Fexofenadine HCI 180 mg

PurposeAntihistamine

*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 useif 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 ifan 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. 1-800-222-1222

Directions

adults and children 12 years and over water once a day; do not take more than 1 caplet in 24 hours children under 12 years of age adults 65 years of age and older consumers with kidney disease

take one 180 mg caplet with do not use ask a doctor ask a doctor

Other information

- store between 20° and 25°C (68° and 77°F)
- **■** protect from excessive moisture

Inactive ingredients

colloidal anhydrous silica, colloidal silicon dioxide, croscarmellose sodium, hypromellose, iron oxide red, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, purified water, titanium dioxide

Ouestions or comments?1-888-333-9792

PRINCIPAL DISPLAY PANEL



FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-5034
Poute 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	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
FERRIC OXIDE YELLOW (UNII: EX43802MRT)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POVIDONE (UNII: FZ989GH94E)		
STARCH, CORN (UNII: O8232NY3SJ)		
WATER (UNII: 059QF0KO0R)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		

Product Characteristics			
Color	orange (Peach)	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	180
Contains			

	ackaging			
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
:	NDC:68210- 5034-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/22/2024	

Marketing I	Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA210137	03/22/2024		