

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

Fexofenadine Hydrochloride Tablets, 180 mg

Drug Facts □

Active ingredient
(in each caplet)
Fexofenadine HCl 180 mg

Purpose Antihistamine

Use 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 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. 1-800-222-1222

Directions

adults and children 12 years and over
water once a day; do not take more than 1
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

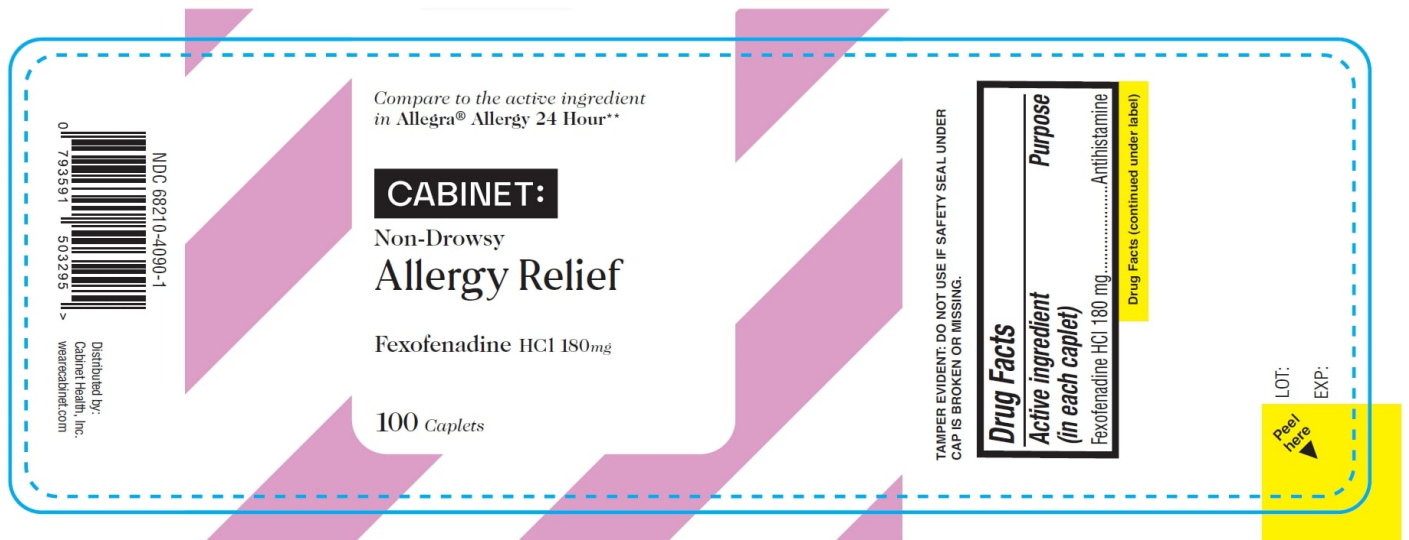
- store between 20° and 25°C (68° and 77°F)
- protect from excessive moisture

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

Questions 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
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
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			

Packaging

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

Marketing Information

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

Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)

