

FEXOFENADINE HCL- fexofenadine hcl tablet, film coated
Spirit Pharmaceuticals LLC

ALLERGY RELIEF, 24 HR (FEXOFENADINE HCl TABLETS USP, 180 mg)

Drug Facts

Active ingredient (in each tablet)

Fexofenadine HCl 180 mg

Purpose

Antihistamine

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 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. You may report side effects to FDA at **1-800-FDA-1088**.

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

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

Drug Facts (continued)

Other information □ safety sealed: do not use 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

Inactive ingredients colloidal silicone dioxide, croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol/macrogol, povidone, pregelatinized starch, red iron oxide, silica, titanium dioxide, yellow iron oxide.

Questions or comments? call **+1-888-333-9792**

PRINCIPAL DISPLAY PANEL

Allergy Relief
Fexofenadine HCl Tablets, 180 mg - Antihistamine

Indoor & Outdoor Allergies

- Sneezing • Runny Nose
- Itchy, Watery Eyes • Itchy Throat Or Nose

Non-Drowsy

4 tablets



FEXOFENADINE HCL

fexofenadine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-4148
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
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange (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:68210-4148-4	1 in 1 CARTON	04/28/2021	
1		4 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210137	04/28/2021	

