FEXOFENADINE HYDROCHLORIDE- fexofenadine hydrochloride tablet
Spirit Pharmaceuticals LLC

Valumeds

FEXOFENADINE

HYDROCHLORIDE

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	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 20º and 25ºC (68º and 77ºF) □ 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**

Distributed by:
Spirit Pharmaceuticals LLC,
Ronkonkoma, NY 11779

ORG 03/19

Manufactured by:
Unique Pharmaceutical
Laboratories
(A Div. of J. B. Chemicals &
Pharmaceuticals Ltd.)
Mumbai 400 030, India
Mfg. Lic. No.: G/1430

PRINCIPAL DISPLAY PANEL

Valumeds™

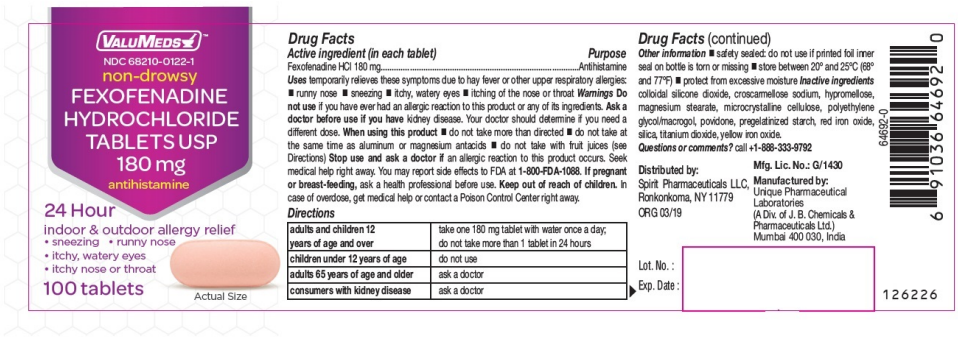
NDC 68210-0122-1
non-drowsy
FEXOFENADINE
HYDROCHLORIDE
TABLETS USP
180 mg
antihistamine

24 Hour

indoor & outdoor allergy relief
• sneezing • runny nose
• itchy, watery eyes
• itchy nose or throat

100 tablets

Actual Size



FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68210-0122
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: 70097M6I30)	
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	**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:68210-0122-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/22/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210137	03/21/2019	

Labeler - Spirit Pharmaceuticals LLC (179621011)

Establishment

Name	Address	ID/FEI	Business Operations
Unique Pharmaceutical Laboratories		650434645	manufacture(68210-0122)

Revised: 4/2019 Spirit Pharmaceuticals LLC