

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

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**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**

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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

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## 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**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68210-4148
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>FEXOFENADINE HYDROCHLORIDE</b> (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	180 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>HYPROMELLOSE 2910 (15 MPA.S)</b> (UNII: 36SFW2JZ0W)	
<b>HYPROMELLOSE 2910 (5 MPA.S)</b> (UNII: R75537T0T4)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6130)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

**Product Characteristics**

<b>Color</b>	orange (ORANGE (PEACH))	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	180
<b>Contains</b>			

**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**

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

