

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

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**Fexofenadine Hydrochloride Tablets, 180 mg**

**Active ingredient (in each caplet)**

Fexofenadine HCl USP 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

**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 and 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 of age and over: take one 180mg 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

### **Other information**

■ store between 20°and 25°C (68°and 77°F)

■ protect from excessive moisture

### **Inactive ingredients**

anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, lactose monohydrate, polyethylene glycol, pregelatinized starch (maize), red iron oxide, stearic acid, titanium dioxide and yellow iron oxide.

### **Questions or comments?**

**1-888-333-9792**

### **PRINCIPAL DISPLAY PANEL**

Compare to the active ingredient  
in Allegra® Allergy 24 Hour†

original prescription strength

ALLERGY RELIEF

Fexofenadine HCl  
tablets USP 180 mg /  
antihistamine

indoor & outdoor allergies

## ALLERGY RELIEF

24 hour relief of:

- sneezing • runny nose
- itchy, watery eyes
- itchy nose or throat

**VALUMEDS™**

Compare to the active ingredient  
in Allegra® Allergy 24 Hour\*  
original prescription strength

**ALLERGY RELIEF**

Fexofenadine HCl  
tablets USP 180 mg /  
antihistamine  
indoor & outdoor  
allergies

24 hour relief of:

- sneezing      • runny nose
- itchy, watery eyes
- itchy nose or throat

**100 tablets**



Actual Size

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL  
UNDER CAP IS BROKEN OR MISSING.

**Drug Facts**

**Active ingredient (in each caplet)** Purpose  
Fexofenadine HCl 180 mg.....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 one caplet
- 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.

**Drug Facts (continued under label)**

This product is not manufactured or distributed by Chatham, Inc., the distributor of Allegra® Allergy 24 Hour.

Distributed By: Spirit Pharmaceuticals, LLC  
Rochester, NY 14779 FEB 11/19  
ITEM# 68924-6



0 40232 68924 6

LOT:

EXP:



<b>Drug Facts (continued)</b>	
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	
<b>Directions</b>	
adults and children 12 years 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
<b>Other information</b>	
<ul style="list-style-type: none"> <li>■ store between 20° and 25°C (68° and 77°F)</li> <li>■ protect from excessive moisture</li> </ul>	
<b>Inactive ingredients</b>	
anhydrous lactose*, colloidal silicon dioxide, corn starch*, croscarmellose sodium, hypromellose, lactose monohydrate*, magnesium stearate*, microcrystalline cellulose*, polyethylene glycol, povidone*, pregelatinized starch, red iron oxide, silica*, stearic acid*, titanium dioxide, yellow iron oxide	
*contains one or more of these ingredients	
<b>Questions or comments? 1-888-333-9792</b>	

## FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68210-2210
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>ANHYDROUS LACTOSE</b> (UNII: 3SY5LH9PMK)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	pink	<b>Score</b>	2 pieces
<b>Shape</b>	OVAL (Capsule shaped, biconvex film coated tablets)	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	SG;202
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-2210-1	100 in 1 PACKAGE; Type 0: Not a Combination Product	03/17/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204507	03/17/2020	

**Labeler** - SPIRIT PHARMACEUTICALS LLC (179621011)

Revised: 12/2024

SPIRIT PHARMACEUTICALS LLC