

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

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 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.

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



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LOT:

EXP:

PEEL HERE



Drug Facts (continued)	
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	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
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consumers with kidney disease	ask a doctor
Other information	
<ul style="list-style-type: none"> ■ 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*, 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	
Questions or comments? 1-888-333-9792	

FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-2210
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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

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

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: 12/2023

SPIRIT PHARMACEUTICALS LLC