

FEXOFENADINE HYDROCHLORIDE- fexofenadine hydrochloride tablet
BluePoint Laboratories

Fexofenadine HCl Tablets USP

Active ingredient(s)

Fexofenadine HCl USP, 180 mg

Purpose

Antihistamine

Use(s)

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- itchy, watery eyes
- sneezing
- 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 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.

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 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

Other information

- safety sealed: do not use if carton is opened or 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
- this product meets the requirements of USP Dissolution Test 4

Inactive ingredients

colloidal silicon dioxide, corn starch, croscarmellose sodium, FD&C Red no. 40, hypromellose, iron oxide black, magnesium stearate, mannitol, polyethylene glycol, powder cellulose and titanium dioxide

Questions?

Call **1-888-375-3784**

PACKAGE LABEL PRINCIPAL DISPLAY PANEL SECTION

NDC 68001-439-00
 Non-Drowsy
Fexofenadine Hydrochloride Tablets, USP
60 mg
 Antihistamine Allergy
INDOOR/OUTDOOR ALLERGY RELIEF
 • Sneezing • Runny Nose
 • Itchy, Watery Eyes • Itchy Nose or Throat
12 Hour
 100 Tablets

BluePoint LABORATORIES

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.
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 60 mg tablet with water every 12 hours; do not take more than 2 tablets 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:
 Do not use if carton was opened or 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
 This product meets the requirements of USP Dissolution Test 4

Inactive ingredients: colloidal silicon dioxide, corn starch, croscarmellose sodium, FD&C Red no. 40, hypromellose, iron oxide black, magnesium stearate, mannitol, polyethylene glycol, powder cellulose and titanium dioxide.

Questions? Call **1-888-375-3784**

Made in India
 REP: 06/20
 Made in India
 150080484
 LOT
 EXP

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You may delete both orange rectangles when art is designed.



Fexofenadine HCL Tablets, 60 mg Carton:



NDC 68001-440-04
Fexofenadine Hydrochloride Tablets USP, 180 mg

Drug Facts (continued)

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

Other information

- safety sealed: do not use if carton is opened or 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
- this product meets the requirements of USP Dissolution Test 4

Inactive ingredients

colloidal silicon dioxide, corn starch, croscarmellose sodium, FD&C Red no. 40, hypromellose, iron oxide black, magnesium stearate, mannitol, polyethylene glycol, powder cellulose and titanium dioxide

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*This product is not manufactured or distributed by Chatterm, Inc. (part of the Sanofi Group), distributor of Allegra® Allergy 24 Hour Tablets. Allegra® is a registered trademark of Aventisub LLC.

Manufactured for:
 Dr. Reddy's Laboratories, Inc.
 Princeton, NJ 08540
 For BluePoint Laboratories

Made in India

REV 05/20

NDC 68001-440-04

Compare to the active ingredient in Allegra® Allergy 24 Hour Tablets*

Non-Drowsy
Fexofenadine Hydrochloride Tablets, USP

180 mg

Antihistamine Allergy

INDOOR/OUTDOOR ALLERGY RELIEF

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Nose or Throat

24 Hour

BluePoint LABORATORIES 30 Tablets

NDC 68001-440-04

Compare to the active ingredient in Allegra® Allergy 24 Hour Tablets*

Non-Drowsy
Fexofenadine Hydrochloride Tablets, USP

180 mg

Antihistamine Allergy

INDOOR/OUTDOOR ALLERGY RELIEF

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Nose or Throat

24 Hour

BluePoint LABORATORIES 30 Tablets

TAMPER EVIDENT: DO NOT USE IF FOIL SEAL UNDER CAP PRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING.

IMPORTANT: Read the directions and warnings before use. Keep the carton. It contains important information.

Drug Facts

Active ingredient (in each tablet)

Fexofenadine HCl USP, 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.

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).



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NDC 68001-440-04

Non-Drowsy
**Fexofenadine Hydrochloride
 Tablets, USP**

180 mg
 Antihistamine
 Allergy

INDOOR/OUTDOOR ALLERGY RELIEF

**BluePoint
 LABORATORIES**

24 Hour
30 Tablets

**TAMPER EVIDENT DO NOT USE IF SEAL IS AL. UNDER
 CAPPRINTED WITH SEAL FOR YOUR
 PROTECTION. DO NOT USE IF WRITING.**

Drug Facts

**Active Ingredient
 (in each tablet)**
 Fexofenadine HCl USP, 180 mg

Purpose
 Antihistamine

Uses Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ runny nose ■ itchy, watery eyes ■ sneezing ■ 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 tell you if you should use this product.

Directions Do not take with fruit juices (see Directions)

Other Information ■ safety sealed, do not use if carton was opened or if printed foil inner seal is torn or missing. ■ Store between 20° and 25°C (68° and 77°F). ■ Keep from moisture. ■ Keep from heat. ■ This product meets the requirements of USP Dissolution Test 4

Inactive Ingredients colloidal silicon dioxide, croscarmellose sodium, Eudragit® L100, magnesium stearate, mannitol, polyethylene glycol, powder cellulose and titanium dioxide.

Questions? Call 1-888-375-3784

Drug Facts (continued)
 Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away, if pregnant or breastfeeding, 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 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

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Manufactured by:
 Dr. Reddy's Laboratories, Inc.
 Princeton, NJ 08540
 For BluePoint Laboratories

Made in India

REV 05/20

150080339

PEEL HERE

LOT

EXP

FOLD PROOF ALONG DOTTED LINE to simulate an actual printed label layout

Drug Facts (continued)
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NDC 68001-440-04

Non-Drowsy
**Fexofenadine Hydrochloride
 Tablets, USP**

180 mg
 Antihistamine
 Allergy

INDOOR/OUTDOOR ALLERGY RELIEF

**BluePoint
 LABORATORIES**

24 Hour
30 Tablets

**TAMPER EVIDENT DO NOT USE IF SEAL IS AL. UNDER
 CAPPRINTED WITH SEAL FOR YOUR
 PROTECTION. DO NOT USE IF WRITING.**

Drug Facts

**Active Ingredient
 (in each tablet)**
 Fexofenadine HCl USP, 180 mg

Purpose
 Antihistamine

Uses Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ runny nose ■ itchy, watery eyes ■ sneezing ■ itching of the nose or throat

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Manufactured by:
 Dr. Reddy's Laboratories, Inc.
 Princeton, NJ 08540
 For BluePoint Laboratories

Made in India

REV 05/20

150080339

PEEL HERE

LOT

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FOLD PROOF ALONG DOTTED LINE to simulate an actual printed label layout

Drug Facts (continued)
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FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:68001-439

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FEXOFENADINE HYDROCHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	60 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
FERROSFERRIC OXIDE (UNII: XMOM87F357)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	pink	Score	no score
Shape	OVAL	Size	4mm
Flavor		Imprint Code	193;R
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68001-439-00	1 in 1 CARTON	06/19/2020	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076502	06/19/2020	

FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68001-440
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	pink	Score	no score
Shape	OVAL	Size	5mm
Flavor		Imprint Code	194;R
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68001-440-00	1 in 1 CARTON	06/19/2020	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:68001-440-04	1 in 1 CARTON	06/19/2020	
2		30 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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ANDA	ANDA076502	06/19/2020	
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Labeler - BluePoint Laboratories (985523874)

Establishment

Name	Address	ID/FEI	Business Operations
DR. REDDY'S LABORATORIES LIMITED		860037244	manufacture(68001-439, 68001-440) , analysis(68001-439, 68001-440)

Establishment

Name	Address	ID/FEI	Business Operations
Dr. Reddy's Laboratories Limited (FTO III)		918608162	analysis(68001-439, 68001-440) , manufacture(68001-439, 68001-440)

Revised: 3/2021

BluePoint Laboratories