FEXOFENADINE HCL- fexofenadine hcl tablet, film coated
Bryant Ranch Prepack

®Tablets

ALLERGY

Active ingredient (in each film-coated tablet)

Fexofenadine HCl USP 60 mg
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

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).

Directions

Directions (for 60mg)

adults and children 12 years of age and over	take one 60mg 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

Directions (for 180mg)

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
- **each tablet contains:**sodium 2.7 mg (for 60 mg), sodium 8.2 mg (for 180 mg)
- this product meets the requirements of USP *Dissolution Test 2*

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?

Call toll-free **1-888-588-1418**
Monday-Friday 9AM-7PM EST

Distributed by: **MAJOR ®PHARMACEUTICALS**
Indianapolis, IN 46268
(800) 616-2471
www.majorpharmaceuticals.com

HOW SUPPLIED

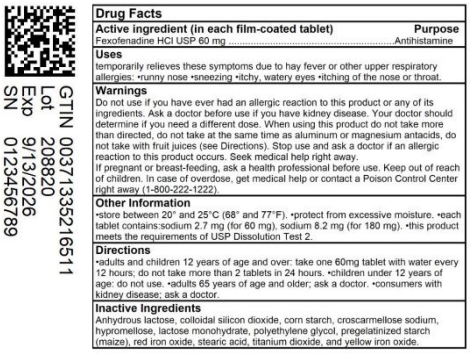
Fexofenadine Hydrochloride Tablets 60 mg

- NDC: 71335-2165-1: 30 Tablets in a BOTTLE
- NDC: 71335-2165-2: 10 Tablets in a BOTTLE
- NDC: 71335-2165-3: 60 Tablets in a BOTTLE
- NDC: 71335-2165-4: 90 Tablets in a BOTTLE
- NDC: 71335-2165-5: 14 Tablets in a BOTTLE
- NDC: 71335-2165-6: 20 Tablets in a BOTTLE
- NDC: 71335-2165-7: 12 Tablets in a BOTTLE

store between 20° and 25°C (68° and 77°F). protect from excessive moisture.

Repackaged/Relabeled by:
Bryant Ranch Prepack, Inc.
Burbank, CA 91504

Fexofenadine Hydrochloride Tablets 60 mg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Lot 208820
Exp 9/13/2026
SN 0123456789

Drug Facts

Active ingredient (in each film-coated tablet) — **Purpose**
Fexofenadine HCl USP 60 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).

Other Information
•store between 20° and 25°C (68° and 77°F). •protect from excessive moisture. •each tablet contains:sodium 2.7 mg (for 60 mg), sodium 8.2 mg (for 180 mg). •this product meets the requirements of USP Dissolution Test 2.

Directions
•adults and children 12 years of age and over: take one 60mg 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.

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.


NDC 71335-2165-1

Fexofenadine HCl Tablets, USP

60 mg

30 Tablets

BRP PHARMACEUTICALS

Repackaged by:
Bryant Ranch Prepack, Inc.
Burbank, CA 91504 USA

Manufactured by:
Major Pharmaceuticals

713352631

Package Insert

FEXOFENADINE HCL

fexofenadine hcl tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71335-2165(NDC:0904-7192)
Route of Administration	ORAL		

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
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	pink	**Score**	no score
Shape	OVAL	**Size**	12mm
Flavor		**Imprint Code**	SG;201
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71335-2165-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	09/06/2024	
2	NDC:71335-2165-2	10 in 1 BOTTLE; Type 0: Not a Combination Product	08/25/2022	
3	NDC:71335-2165-3	60 in 1 BOTTLE; Type 0: Not a Combination Product	09/06/2024	
4	NDC:71335-2165-4	90 in 1 BOTTLE; Type 0: Not a Combination Product	09/06/2024	
5	NDC:71335-2165-5	14 in 1 BOTTLE; Type 0: Not a Combination Product	09/06/2024	
6	NDC:71335-2165-6	20 in 1 BOTTLE; Type 0: Not a Combination Product	09/06/2024	
7	NDC:71335-2165-7	12 in 1 BOTTLE; Type 0: Not a Combination Product	11/08/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204507	08/26/2021	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(71335-2165) , RELABEL(71335-2165)

Revised: 9/2024