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

® Tablets

ALLERGY

Active ingredient (in each film-coated tablet)

Fexofenadine HCI USP 60 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

adults and children 12 years	take one 60mg tablet with water every 12 hours; do not	
of age and over	take more than 2 tablets in 24 hours	
children under 12 years of age do not use		
adults 65 years of age and	ask a doctor	
older		
consumers with kidney	ask a doctor	
disease		

Other information

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

Inactive ingredients

anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, lactose monohydrate, pregelatinized starch(maize), stearic acid, opadry pink 03B84893 containing hypromellose, polyethylene glycol, red iron oxide titanium dioxide and yellow iron oxide.

Questions or comments?

Call toll-free 1-800-616-2471

HOW SUPPLIED

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

Fexofenadine Hcl 60mg Tablet



Each tablet contains: Fexofenadine Hcl 60 mg

Keep this and all drugs out of the reach of children.

Store at 20° to 25° C (68° to 77° F); excursions permitted to 15° to 30° C (59° to 86° F) (see USP controlled Room Temperature).

NDC 71335-**2165**-1

Fexofenadine HCI Tablets, USP

60 mg

BRP

30 Tablets

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

Manufactured by: ScieGen Pharmaceuticals, Inc.



FEXOFENADINE HCL

fexofenadine hcl tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION 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: M280L1HH48)			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
FERRIC OXIDE RED (UNII: 1K09F3G675)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
FERRIC OXIDE YELLOW (UNII: EX43802MRT)			

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	08/29/2022	
2	NDC:71335- 2165-2	10 in 1 BOTTLE; Type 0: Not a Combination Product	08/29/2022	
3	NDC:71335- 2165-3	60 in 1 BOTTLE; Type 0: Not a Combination Product	08/29/2022	
4	NDC:71335- 2165-4	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/29/2022	
5	NDC:71335- 2165-5	14 in 1 BOTTLE; Type 0: Not a Combination Product	08/29/2022	
6	NDC:71335- 2165-6	20 in 1 BOTTLE; Type 0: Not a Combination Product	08/29/2022	

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: 1/2024 Bryant Ranch Prepack