FEXOFENADINE HCL- fexofenadine hcl tablet
Bryant Ranch Prepack

Fexofenadine Hydrochloride Tablets USP, 180 mg

ACTIVE INGREDIENT(S), in each tablet

Fexofenadine hydrochloride USP, 180 mg

PURPOSE

Antihistamine

USE(S)

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.

DIRECTIONS

60 mg

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

180 mg

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 the bottle is torn or missing.
- ☐ store between 20° and 25°C (68° and 77°F)
- ☐ protect from excessive moisture

INACTIVE INGREDIENTS

Colloidal silicon dioxide, hypromellose, light liquid paraffin, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, pregelatinized starch, red iron oxide, sodium starch glycolate, talc, titanium dioxide and yellow iron oxide.

QUESTIONS OR COMMENTS

call toll-free weekdays 9 AM to 5 PM EST at **1-888-588-1418**

Fexofenadine Hcl 180mg Tablet

Drug Facts

Active ingredients (in each tablet) — **Purpose**
Fexofenadine hydrochloride 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. If pregnant or breast-feeding, ask a health professional before use. Keep out of reach children. In case of overdose, get medical help or contact a Poison Control Center right away.

Other Information
•Safety Sealed: do not use if carton is opened or if printed foil inner seal on the bottle is torn or missing. •store between 20° and 25°C (68° and 77°F). •protect from excessive moisture. •Scan Package Insert QR Code for more information.

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. •adults and children 12 years of age and over; take one 180 mg tablet with water every 12 hours; do not take more than 1 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.

Inactive Ingredients
Colloidal silicon dioxide, hypromellose, light liquid paraffin, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, pregelatinized starch, red iron oxide, sodium starch glycolate, talc, titanium dioxide and yellow iron oxide.

GTIN 00371335121716
Lot 208820
Exp 8/23/2026
SN 0123456789

Package Insert

NDC 71335-1217-1

Fexofenadine Hydrochloride Tablets, USP

180 mg

30 Tablets

BRP PHARMACEUTICALS

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

Manufactured by:
Hetero Labs Limited
Unit V

713351217

FEXOFENADINE HCL

fexofenadine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71335-1217(NDC:69230-300)
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)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STARCH, CORN (UNII: O8232NY3SJ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	

Product Characteristics

Color	PINK	**Score**	no score
Shape	CAPSULE	**Size**	18mm
Flavor		**Imprint Code**	J;44
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71335-1217-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2019	
2	NDC:71335-1217-2	15 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2019	
3	NDC:71335-1217-3	60 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2019	
4	NDC:71335-1217-4	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2019	
5	NDC:71335-1217-5	5 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2019	
6	NDC:71335-1217-6	180 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2019	
7	NDC:71335-1217-7	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204097	08/19/2016	

Labeler - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(71335-1217) , RELABEL(71335-1217)

Revised: 8/2024

Bryant Ranch Prepack