FEXOFENADINE HYDROCHLORIDE- fexofenadine hydrochloride tablet
Dr. Reddy's Laboratories Limited

Fexofenadine HCl Tablets USP

Active ingredient(s)

Fexofenadine HCl USP, 30 mg

Fexofenadine HCl USP, 60 mg

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.

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

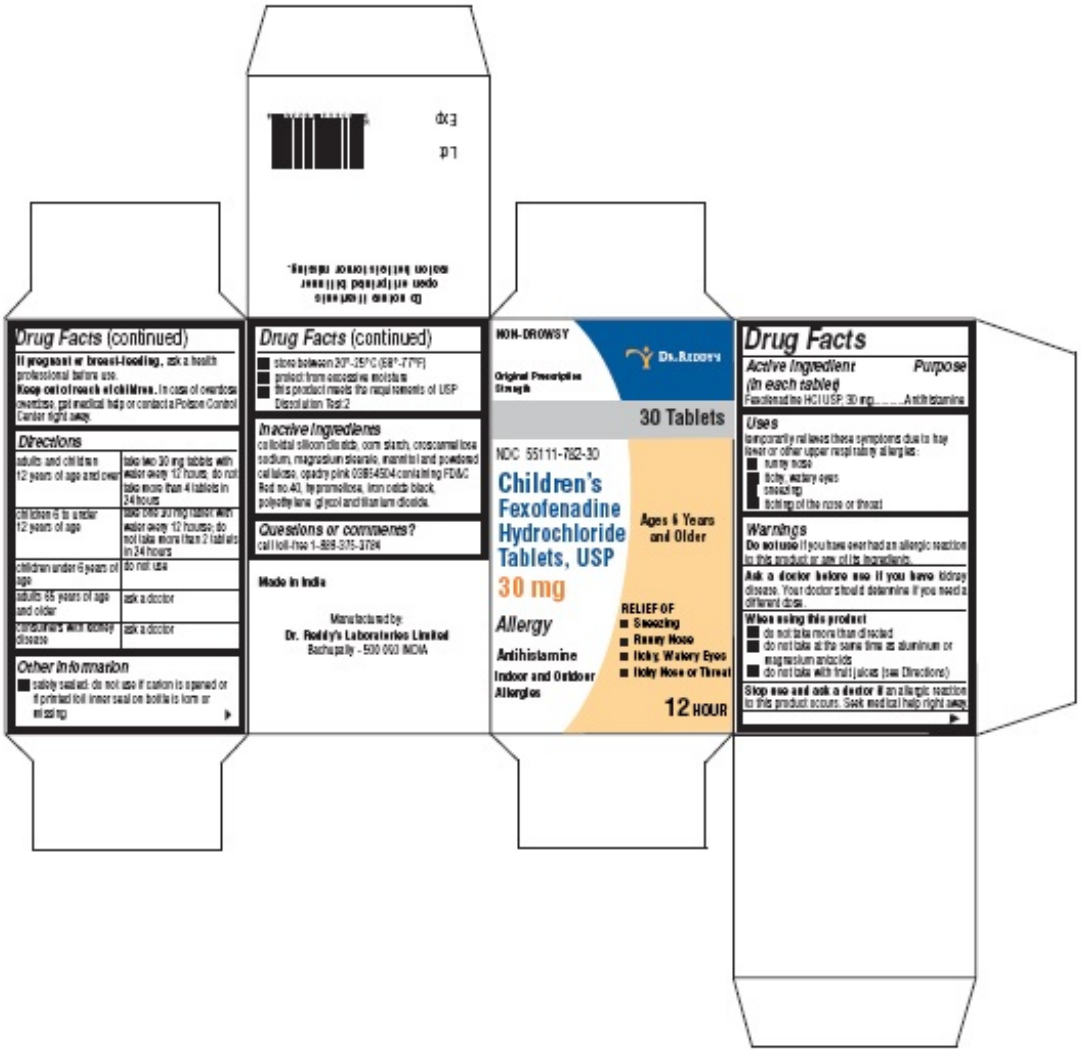
Questions?

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

PACKAGE LABEL PRINCIPAL DISPLAY PANEL SECTION

Bottle label:

Fexofenadine HCl Tablets, 30 mg Carton:



Fexofenadine HCl Tablets USP, 60 mg Carton:

Fexofenadine HCl Tablets USP, 180 mg Carton Label:

FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55111-782
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Fexofenadine Hydrochloride (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	Fexofenadine Hydrochloride	30 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE 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)	
FERROSOFERRIC 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**	4mm
Flavor		**Imprint Code**	192;R
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55111-782-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2011	
2	NDC:55111-782-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2011	
3	NDC:55111-782-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2011	
4	NDC:55111-782-78	10 in 1 CARTON	01/03/2011	
4	NDC:55111-782-79	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076502	01/03/2011	

FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55111-783
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE 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)	
FERROSOFERRIC 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**	193;R
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55111-783-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2011	
2	NDC:55111-783-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2011	
3	NDC:55111-783-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2011	
4	NDC:55111-783-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2011	
5	NDC:55111-783-78	10 in 1 CARTON	01/03/2011	
5	NDC:55111-783-79	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:55111-783-28	2 in 1 CARTON	12/01/2020	
6		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
7	NDC:55111-783-24	4 in 1 CARTON	12/01/2020	
7		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076502	01/03/2011	

FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55111-784
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)	
CROSCARMELLOSE 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)	
FERROSOFERRIC 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**	7mm
Flavor		**Imprint Code**	194;R
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55111-	1 in 1 CARTON	01/03/2011	

1	784-30	1 in 1 CARTON	01/03/2011	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:55111-784-43	2 in 1 CARTON	01/03/2011	
2		30 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:55111-784-40	1 in 1 CARTON	01/03/2011	
3		40 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:55111-784-45	1 in 1 CARTON	01/03/2011	
4		45 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:55111-784-59	2 in 1 CARTON	01/03/2011	
5		60 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:55111-784-75	1 in 1 CARTON	01/03/2011	
6		70 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:55111-784-90	1 in 1 CARTON	01/03/2011	
7		90 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:55111-784-01	1 in 1 CARTON	01/03/2011	
8		100 in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:55111-784-15	1 in 1 CARTON	01/03/2011	
9		150 in 1 BOTTLE; Type 0: Not a Combination Product		
10	NDC:55111-784-18	1 in 1 CARTON	01/03/2011	
10		180 in 1 BOTTLE; Type 0: Not a Combination Product		
11	NDC:55111-784-05	1 in 1 CARTON	01/03/2011	
11		500 in 1 BOTTLE; Type 0: Not a Combination Product		
12	NDC:55111-784-23	1 in 1 CARTON	01/03/2011	
12		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
13	NDC:55111-784-07	1 in 1 CARTON	01/03/2011	
13		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
14	NDC:55111-784-35	2 in 1 CARTON	12/01/2021	
14		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
15	NDC:55111-784-29	3 in 1 CARTON	01/03/2011	
15		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
	NDC:55111			

16	NDC:55111-784-78	10 in 1 CARTON	01/03/2011	
16	NDC:55111-784-79	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
17	NDC:55111-784-28	3 in 1 CARTON	01/03/2011	
17		15 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076502	01/03/2011	

Labeler - Dr. Reddy's Laboratories Limited (650562841)

Establishment

Name	Address	ID/FEI	Business Operations
Dr. Reddy's Laboratories Limited (FTO III)		918608162	analysis(55111-784, 55111-782, 55111-783) , manufacture(55111-784, 55111-782, 55111-783)

Establishment

Name	Address	ID/FEI	Business Operations
Reed-Lane, Inc.		001819879	repack(55111-784, 55111-782, 55111-783)

Establishment

Name	Address	ID/FEI	Business Operations
Quality Packaging Specialists International, LLC		080629831	repack(55111-784)

Establishment

Name	Address	ID/FEI	Business Operations
Dr. Reddy's Laboratories Louisiana, LLC		830397282	repack(55111-784)

Establishment

Name	Address	ID/FEI	Business Operations
DR. REDDY'S LABORATORIES LIMITED		860037244	repack(55111-784, 55111-783) , analysis(55111-783) , manufacture(55111-783)