

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

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**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:

Dr.Reddy's  NDC 55111-784-30  
 Original Prescription Strength • Non-Drowsy  
**Fexofenadine**  
 Hydrochloride  
 Tablets USP, 180 mg   
 Antihistamine  
**ALLERGY** Indoor & Outdoor Allergies  
 30 Tablets  
 180 mg each

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

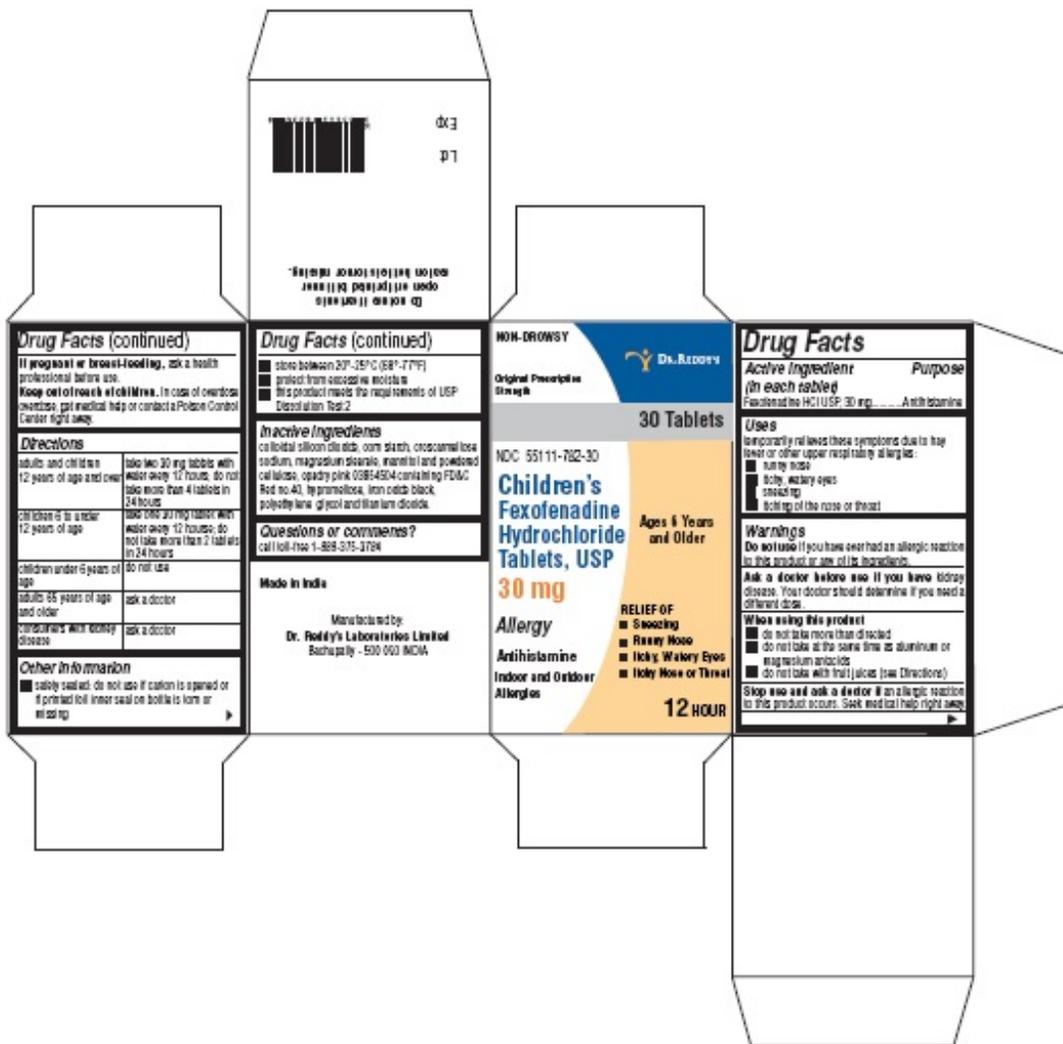
**Drug Facts**  
**Active ingredient**  
 Fexofenadine HCl USP,  
 180 mg .....Antihistamine  
**Purpose**  
 (in each tablet)  
**Uses** Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ runny nose ■ itchy, watery eyes ■ sneezing ■ itching of the nose or throat  
**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 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)  
 (Continued On Back Of Label)

Distributed by: Dr. Reddy's Laboratories, Inc.  
 Princeton, NJ 08540  
 Made in India

150073821  
 LOT  
 EXP  
 PEEL HERE 

**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 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 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

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

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55111-782
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Fexofenadine Hydrochloride</b> (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	Fexofenadine Hydrochloride	30 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>magnesium stearate</b> (UNII: 70097M6I30)	
<b>mannitol</b> (UNII: 3OWL53L36A)	
<b>POWDERED CELLULOSE</b> (UNII: SMD1X3XO9M)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>HYPROMELLOSE 2910 (6 MPA.S)</b> (UNII: 0WZ8WG20P6)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>polyethylene glycol 400</b> (UNII: B697894SGQ)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	

### Product Characteristics

<b>Color</b>	PINK	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	4mm
<b>Flavor</b>		<b>Imprint Code</b>	192;R
<b>Contains</b>			

### 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

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55111-783
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Fexofenadine Hydrochloride</b> (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	Fexofenadine Hydrochloride	60 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>magnesium stearate</b> (UNII: 70097M6I30)	
<b>mannitol</b> (UNII: 3OWL53L36A)	
<b>POWDERED CELLULOSE</b> (UNII: SMD1X3XO9M)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>HYPROMELLOSE 2910 (6 MPA.S)</b> (UNII: 0WZ8WG20P6)	
<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>polyethylene glycol 400</b> (UNII: B697894SGQ)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	

**Product Characteristics**

<b>Color</b>	PINK	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	5mm
<b>Flavor</b>		<b>Imprint Code</b>	193;R
<b>Contains</b>			

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:55111-783-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2011	03/30/2024
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
<b>Fexofenadine Hydrochloride</b> (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	Fexofenadine Hydrochloride	180 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>POWDERED CELLULOSE</b> (UNII: SMD1X3XO9M)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>HYPROMELLOSE 2910 (6 MPA.S)</b> (UNII: 0WZ8WG20P6)	
<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>STARCH, CORN</b> (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 is 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	pack(55111-782, 55111-783, 55111-784)

## Establishment

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

Revised: 5/2025

Dr. Reddy's Laboratories Limited