

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

Fexofenadine HCl Tablets USP

Active ingredient(s)

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

Storage

- 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**

Carton label



TAMPER EVIDENT: DO NOT USE IF FOLK SEAL UNDER CAP PRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING
IMPORTANT: Read the directions and warnings before use. Keep the carton. It contains important information.

Drug Facts

Active ingredient (in each tablet)	Purpose
Fexofenadine HCl USP, 180 mg	Antihistamine

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)
 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
 • safely 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: calcium silicate dihydrate, 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 1-888-376-3764

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

Made in India

*This product is not manufactured or distributed by Chiltern, Inc., part of the Sanofi Group, distributor of Allegra® Allergy 24 Hour Tablets. Allegra® is a registered trademark of Aventis LLC.

Bottle label

Original Prescription Strength
Non-Drowsy

Allergy Relief

Fexofenadine Hydrochloride
Tablets USP, 180 mg

ANTIHISTAMINE

Indoor and Outdoor Allergies

180 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	Purpose Fexofenadine HCl USP, 180 mg.....Antihistamine
Active Ingredient (in each tablet)	Fexofenadine HCl USP, 180 mg.....Antihistamine
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) 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

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

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LOT
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FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43598-809(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)	
CROSCARMELOSE 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)	
FERROSO FERRIC 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:43598-809-90	1 in 1 CARTON	12/26/2018	
1		90 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:43598-809-18	1 in 1 CARTON	12/26/2018	
2		180 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076502	12/26/2018	

Labeler - Dr. Reddy's Laboratories Inc. (802315887)**Establishment**

Name	Address	ID/FEI	Business Operations
Dr. Reddy's Laboratories Limited (FTO III)		918608162	analysis(43598-809) , manufacture(43598-809)

Establishment

Name	Address	ID/FEI	Business Operations
Reed-Lane, Inc.		001819879	repack(43598-809)

Revised: 12/2018

Dr. Reddy's Laboratories Inc.