

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

Fexofenadine HCl Tablets USP

Active ingredient(s)

Fexofenadine HCl USP, 60 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 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

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

Container:

HealthCare  Aisle

NDC 43598-936-30

Non-Drowsy

Allergy Relief

Fexofenadine Hydrochloride Tablets, USP
60 mg

Antihistamine

12
HR

30 Tablets
60 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 (in each tablet)
Fexofenadine HCl USP, 60 mg.....Antihistamine

Purpose
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

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- 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

REV 08/20

150081715

LOT
PEEL HERE
EXP

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 (1-800-222-1222).

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 ■ **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

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Questions ? Call 1-888-375-3784

Carton:

917 180051



TAMPER EVIDENT: DO NOT USE IF FOIL 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

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HealthCare  Aisle

Non-Drowsy

Allergy Relief

Fexofenadine Hydrochloride Tablets USP, 60 mg
Antihistamine

HealthCare  Aisle

NDC 43598-936-30

Compare to the active ingredient in Allegra® Allergy 12 Hour Tablets*

Non-Drowsy

Allergy Relief

Fexofenadine Hydrochloride Tablets, USP
60 mg

Antihistamine

Indoor/Outdoor Allergy Relief

- Sneezing
- Itchy, Watery Eyes
- Runny Nose
- Itchy Nose or Throat

12
HR



actual size

30 Tablets
60 mg each



3 43598 93630 7

HealthCare  Aisle

Non-Drowsy

Allergy Relief

Fexofenadine Hydrochloride Tablets USP, 60 mg
Antihistamine

FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43598-936(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)	
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: OWZ8WG20P6)	
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	5mm
Flavor		Imprint Code	193;R
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43598-936-30	1 in 1 CARTON	12/01/2020	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:43598-936-01	1 in 1 CARTON	12/01/2020	
2		100 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	12/01/2020	

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

Revised: 8/2021

Dr. Reddy's Laboratories Inc.