

FEXOFENADINE HYDROCHLORIDE- fexofenadine hydrochloride tablet
KROGER COMPANY

Fexofenadine HCl Tablets USP

Active ingredient (in each tablet)

Fexofenadine HCl USP, 180 mg

Purpose

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 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 - 30 Count Carton





NDC 30142-878-30

24 HOUR

**ORIGINAL PRESCRIPTION STRENGTH
NON-DROWSY**

Allergy Relief

**Fexofenadine Hydrochloride
Tablets USP, 180 mg**

Antihistamine

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	Purpose
Active ingredient (in each tablet) Fexofenadine HCl USP, 180 mg, 181 mg	Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: <input type="checkbox"/> runny nose <input type="checkbox"/> itchy, watery eyes <input type="checkbox"/> sneezing <input type="checkbox"/> itching of the nose or throat
Uses	Warnings Do not use if you have ever had an allergic reaction to this product or any of its ingredients.
Directions	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)
Other information	Directions (Continued On Back Of Label)

**DISTRIBUTED BY THE KROGER CO.
CINCINNATI, OHIO 45202**

MADE IN INDIA

QUALITY GUARANTEE
www.kroger.com

150073829

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 1-800-632-6900

FEXOFENADINE HYDROCHLORIDE			
fexofenadine hydrochloride tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-878(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:30142-878-30	1 in 1 CARTON	09/30/2018	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:30142-878-15	3 in 1 CARTON	09/30/2018	
2		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:30142-878-70	1 in 1 CARTON	09/30/2018	
3		70 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:30142-878-64	2 in 1 CARTON	01/10/2019	
4		70 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	09/30/2018	

Labeler - KROGER COMPANY (006999528)

Revised: 1/2020

KROGER COMPANY