

FEXOFENADINE HCL- fexofenadine hcl tablet, film coated
Advanced Rx LLC

Active ingredient (in each tablet)

Fexofenadine HCl 180 mg

Purpose

Antihistamine

Uses

Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- 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 (1-800-222-1222) right away.

Directions

adults and children 12 years of age and over	take one 180mg 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

- store between 20° and 25°C (68° and 77°F)
- protect from excessive moisture
- **each tablet contains:**sodium 8.2 mg
- this product meets the requirements of *USP Dissolution Test 2*
- **DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED**

Inactive ingredients

anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, lactose monohydrate, polyethylene glycol, pregelatinized starch (maize), red iron oxide, stearic acid, titanium dioxide, and yellow iron oxide

Questions?

call toll free **1-800-630-8895**

Distributed by:

Advanced Rx LLC

1942 NE 163rd St North Miami Beach,
FL 33162 U.S.A.

Package/Label Principal Display Panel

NDC 80513-506-01

Compare to the active ingredient in Allegra[®] Allergy 24 Hour Tablets *

Non-Drowsy

Allergy Relief

Fexofenadine HCL 180 mg

INDOOR & OUTDOOR ALLERGY

24-Hour Allergy Relief Of:

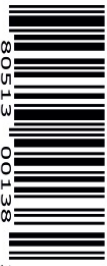
- Sneezing, runny nose


- Itchy, watery eyes
- Itchy throat or nose

100 Tablets

*This product is not manufactured or distributed by the owner of the registered trademark Allegra® Allergy 24 Hour Tablets.

N 8E100 S1S08 E





Compare to the active ingredient in Allegra® Allergy 24 Hour Tablets*
NDC 80513-506-01

NON-DROWSY

ALLERGY RELIEF

24 HOUR Allergy Relief Of:

- ✓ Sneezing, runny nose
- ✓ Itchy, watery eyes
- ✓ Itchy throat or nose

FEXOFENADINE HCL 180 MG

Original Prescription Strength

INDOOR & OUTDOOR ALLERGY

100

TABLETS

DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED

Drug Facts

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

Uses
Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- 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 (1-800-222-1222) right away.

PEEL FOR DIRECTIONS G7022-100-106-0

LIFT HERE

Drug Facts (continued)

Directions	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 and older	ask a doctor
consumers with kidney disease	ask a doctor

Other information

- store between 20° and 25°C (68° and 77° F)
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- each tablet contains: sodium 8.2 mg
- this product meets the requirements of USP Dissolution Test 2

Inactive ingredients
anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, lactose monohydrate, polyethylene glycol, pregelatinized starch (maize), red iron oxide, stearic acid, titanium dioxide, yellow iron oxide.

Questions? call toll-free 1-800-630-8895

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ADVANCED RX LLC
1942 NE 163rd St
North Miami Beach, FL
33162 U.S.A.

FEXOFENADINE HCL

fexofenadine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80513-506
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FEXOFENADINE HYDROCHLORIDE (UNII: 2S068B75Z U) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	180 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	pink	Score	no score
Shape	OVAL	Size	18mm
Flavor		Imprint Code	SG202
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80513-506-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/10/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204507	09/16/2015	

Labeler - Advanced Rx LLC (042795108)

Revised: 9/2024

Advanced Rx LLC