

FEXOFENADINE HCL- fexofenadine hcl tablet
Shopko Stores Operating Co., LLC.

DRUG FACTS

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
- 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

- store at 20°-25°C (68°-77°F)
- protect from excessive moisture

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, hypromellose, iron oxide red, iron oxide yellow, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone k-30, talc, titanium dioxide.

Questions or comments?

call toll free 1-877-753-3935 Monday- Friday 9AM- 5PM EST

Package/Label Principal Display Panel

*Compare to the active ingredient in Allegra® Allergy 24 hour

ORIGINAL PRESCRIPTION STRENGTH

NON-DROWSY

Fexofenadine HCl tablets, USP 180 mg

Antihistamine

24 Hour Relief of:

sneezing

runny nose

itchy, watery eyes

itchy nose or throat

*This product is not manufactured or distributed by Chattem Inc., distributor of Allegra® Allergy 24 hour

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

SAFETY SEALED: DO NOT USE IF CARTON IS OPEN OR IF INNER SEAL IMPRINTED WITH "SEALED FOR YOUR PROTECTION" IS MISSING OR TORN

Packaged by: PL Developments

200 hicks street

westbury NY 11590

Product Label



FEXOFENADINE HCL 180 mg

FEXOFENADINE HCL

fexofenadine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:370 12-189
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FEXO FENADINE HYDRO CHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	180 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONES (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	WHITE (Light peach)	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	W987
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37012-189-30	1 in 1 BOX		
1		30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079112	06/11/2012	

Labeler - Shopko Stores Operating Co., LLC. (023252638)

Revised: 8/2012

Shopko Stores Operating Co., LLC.