

FEXOFENADINE HCL- fexofenadine hcl tablet
Chain Drug Marketing Association

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 **248-449-9300**

Package/Label Principal Display Panel

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

ORIGINAL PRESCRIPTION STRENGTH

Fexofenadine HCl tablets 180 mg/ Antihistamine

INDOOR & OUTDOOR ALLERGIES

NON-DROWSY

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.
DO NOT USE IF CARTON IS OPEN OR IF INDIVIDUAL BLISTER IS TORN OR OPEN.**

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

Distributed by C.D.M.A., Inc.

43157 W. Nine Mile

Novi, MI 48376-0995

www.qualitychoice.com

Questions: 248-449-9300

Product Label

110324Q1A

PRINT SIDE GLUE

NO INK
NO VARNISH

NO INK
NO VARNISH

Drug Facts

Active ingredient (in each tablet)
Fexofenadine HCl 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;
 children under 12 years of age
 do not take more than 1 tablet in 24 hours

ask a doctor	ask a doctor
ask a doctor	ask a doctor
ask a doctor	ask a doctor
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Other information
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Questions or comments? Call 248-449-9300



Original Prescription Strength

Fexofenadine HCl Tablets, USP 180 mg/Antihistamine Non-Drowsy



NDC 63868-024-15

***Compare to the active
ingredient in ALLEGRA®
ALLERGY 24 HOUR**

Original Prescription Strength

Fexofenadine HCl Tablets, USP 180 mg/Antihistamine

Indoor & Outdoor Allergies

Non-Drowsy

24 Hour Relief of:
Sneezing | Runny Nose
Itchy, Watery Eyes
Itchy Nose or Throat



15 Tablets (180 mg each)

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Novi, MI 48376-0995
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PLD-A
FC000543



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KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.
DO NOT USE IF CARTON IS OPEN OR IF INDIVIDUAL BLISTER UNIT IS TORN OR OPEN.

Lot No.:
Exp. Date:

Fexofenadine Hcl 180 mg 15 count

FEXOFENADINE HCL

fexofenadine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-024
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
SILICON DIO XIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE 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 DIO XIDE (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:63868-024-15	1 in 1 CARTON		
1		15 in 1 BLISTER PACK		
2	NDC:63868-024-30	1 in 1 BOX		
2		30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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ANDA	ANDA079112	08/27/2012	
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Labeler - Chain Drug Marketing Association (011920774)

Revised: 8/2012

Chain Drug Marketing Association