

FEXOFENADINE HCL- fexofenadine hcl tablet, film coated
Lake Erie Medical DBA Quality Care Products LLC

FEXOFENADINE HYDROCHLORIDE TABLETS USP, 180 mg
Allergy

ALLERGY

Active ingredient (in each film-coated 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 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 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

- 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
- 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, lactose monohydrate, pregelatinized starch (maize), stearic acid, opadry pink 03B84893 containing hypromellose, polyethylene glycol, red iron oxide, titanium dioxide and yellow iron oxide.




Questions or comments?

Call 1-888-588-1418

Distributed by:

Camber Consumer Care, Inc.
Piscataway, NJ 08854, USA,

Made in USA

Packaged and Distributed by <i>Quality Care Products, LLC</i> 1-800-337-8603		
	<p>Holland, OH 43528</p> <p>ALLERGY RELIEF FEXOFENADINE HCl 180 MG</p> <p>GTIN: 00355700500603</p> <p>NDC: 55700-0500-60</p> <p>Serial: #60 TABLETS</p> <p>Lot: Antihistamine</p> <p>EXP: //</p> <p>Each tablet contains Fexofenadine Hydrochloride</p> <p>Distributed by: Camber Consumer Care, Inc., Piscataway, NJ 08854, USA</p>	<p>Warning: Keep out of children's reach.</p> <p>Store at controlled temperature 68-77 degrees F.</p> <p>Consult with a physician. See manufacturer's insert.</p> <p>PINK, CAPSULE, SG;202</p> 
	<p>ALLERGY RELIEF FEXOFENADINE HCl 180 MG #60 TABLETS Lot: EXP: // NDC: 55700-0500-60</p>	<p>ALLERGY RELIEF FEXOFENADINE HCl 180 MG #60 TABLETS Lot: EXP: // NDC: 55700-0500-60</p>
		 <p style="font-size: 8px;">SOURCE CODE : 6923020201</p>

FEXOFENADINE HCL

fexofenadine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55700-500(NDC:69230-202)
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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
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSES (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	CAPSULE	Size	17mm
Flavor		Imprint Code	SG;202
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55700-500-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/10/2017	10/11/2019
2	NDC:55700-500-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/08/2017	10/11/2019
3	NDC:55700-500-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2017	

Marketing Information

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

Labeler - Lake Erie Medical DBA Quality Care Products LLC (831276758)

Establishment

Name	Address	ID/FEI	Business Operations
Lake Erie Medical DBA Quality Care Products LLC		831276758	repack(55700-500)

Revised: 10/2019

Lake Erie Medical DBA Quality Care Products LLC