

FEXOFENADINE HYDROCHLORIDE- fexofenadine hydrochloride tablet
NuCare Pharmaceuticals, Inc.

Fexofenadine HCl Tablets USP

Active ingredient(s)

Fexofenadine HCl USP, 180 mg

Purpose

Antihistamine

Use(s)

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

NuCare Pharmaceuticals, Inc.

NDC: 68071-5191-3
Fexofenadine HCl 180mg
#30 Tablets
 See manufacturer's label for full list of ingredients.

Product #: R1867030

GTIN 00368071519136
 Serial# 0000000002
 Exp. Date 00-00
 LOT#: 000000

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

WARNING: KEEP OUT OF REACH OF CHILDREN STORE AT CONTROLLED TEMPERATURE 68-77°F.

FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68071-5191(NDC:55111-784)
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)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYPROMELLOSE 2910 (6 MPAS) (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:68071-5191-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076502	01/03/2011	

Labeler - NuCare Pharmaceuticals, Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals, Inc.		010632300	relabel(68071-5191)

Revised: 3/2020

NuCare Pharmaceuticals, Inc.