

**FEXOFENADINE HYDROCHLORIDE- fexofenadine hydrochloride tablet, film coated**

**NuCare Pharmaceuticals, Inc.**

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**Active ingredient(in each tablet)**

Fexofenadine HCl USP, 180 mg

Fexofenadine HCl USP, 60 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 aluminium 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

adults and children 12 years of age and over	take one 60 mg tablet with water every 12 hours; do not take more than 2 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 and light

## Inactive ingredients

anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, lactose monohydrate, polyethylene glycol 400, pregelatinized corn starch, red iron oxide, steric acid, titanium dioxide, and yellow iron oxide,

## Questions or comments?

call 1-855-274-4122

## Principal Display Panel


NuCare Pharmaceuticals, Inc.

**NDC: 68071-1896-9**

**Fexofenadine HCl 180mg**

**#90 Tablets**

Each tablet contains:  
Fexofenadine HCl USP, 180mg. Antihistamine 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. In case of overdose, get medical help or contact a Poison Control Center right away. Oblong Peach Tablet Debossed: "44" on one side "E" on the other side

**Product #: P1349090**

**Fexofenadine HCl 180mg**  
Lot: 000000 NDC: 68071-1896-09  
MFR NDC: 58602-711-21 Exp.: 00-00

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**Fexofenadine HCl 180mg**  
Lot: 000000 NDC: 68071-1896-09  
MFR NDC: 58602-711-21 Exp.: 00-00

GTIN 00368071189698  
Serial# 00000000002  
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.

Rev 01/01/19

**WARNING: KEEP OUT OF REACH OF CHILDREN**

**STORE AT CONTROLLED TEMPERATURE 68-77°F.**

## FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b> NDC:68071-1896(NDC:58602-711)
<b>Route of Administration</b>	ORAL	

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>FEXOFENADINE HYDROCHLORIDE</b> (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	180 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS LACTOSE</b> (UNII: 3SY5LH9PMK)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>STARCH, PREGELATINIZED CORN</b> (UNII: O8232NY3SJ)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	orange (Peach)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (Bevel Edge, Biconvex)	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	E;44
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-1896-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/28/2017	
2	NDC:68071-1896-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/28/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202039	01/15/2015	

**Labeler** - NuCare Pharmaceuticals, Inc. (010632300)

### Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals, Inc.		010632300	repack(68071-1896)

Revised: 2/2021

NuCare Pharmaceuticals, Inc.