

**FEXOFENADINE HYDROCHLORIDE- fexofenadine hcl tablet, film coated  
NuCare Pharmaceuticals, Inc.**

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**Major Pharmaceuticals Fexofenadine Hydrochloride Tablets, 60 mg Drug  
Facts**

**Active ingredient (in each tablet)**

Fexofenadine HCl 60 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 (1-800-222-1222).

## Directions

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 tablets 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

- do not use if carton is opened or printed foil under cap is broken or missing
- store between 20 °-25 °C (68 °-77 °F)
- protect from excessive moisture
- this product meets the requirements of USP *Dissolution Test 3*

## Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, titanium dioxide

## Questions or comments?

1-800-719-9260

## Package/Label Principal Display Panel

**NuCare Pharmaceuticals, Inc.**

NDC: 68071-5185-9

**Fexofenadine HCl 60mg**

**#90 Tablets**

Each tablet contains: Fexofenadine HCl 60mg.....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 (1-800-222-1222) Round Peach Tablet Debossed: "90" on one side "7252" on the other side

Product #: P1402090

GTIN 00368071518597  
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.

Take \_\_\_\_\_ times a day, every \_\_\_\_\_ hours

Rev 01/01/19  
WARNING: KEEP OUT OF REACH OF CHILDREN  
STORE AT CONTROLLED TEMPERATURE 68-77°F.

# FEXOFENADINE HYDROCHLORIDE

fexofenadine hcl tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68071-5185(NDC:0904-6979)
<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	60 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	orange (Peach)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	93;7252
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-5185-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/26/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076447	08/08/2011	

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

**Establishment**

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals, Inc.		010632300	repack(68071-5185)

Revised: 2/2022

NuCare Pharmaceuticals, Inc.