# FEXOFENADINE HCL- fexofenadine hcl tablet, film coated NuCare Pharmaceuticals, Inc.

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#### **ALLERGY**

### Active ingredient (in each film-coated tablet)

Fexofenadine HCI 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 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	take one 60mg tablet with water every 12 hours; do not		
of age and over	take more than 2 tablets in 24 hours		
children under 12 years of age do not use			
adults 65 years of age and	ask a doctor		
older			
consumers with kidney	ask a doctor		
disease			

#### Other information

- store between 20° and 25°C (68° and 77°F)
- protect from excessive moisture
- each tablet contains: sodium 2.7mg(for 60 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 toll-free 1-800-616-2471

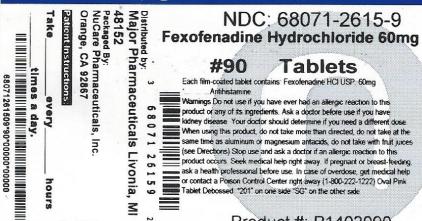
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**MAJOR ® PHARMACEUTICALS** 

Livonia, MI 48152

Package/Label Principal Display Panel

# NuCare Pharmaceuticals, Inc.



Fexofenadine Hydrochloride 60mg
Lot: 00000 NDC: 68071-2615-09
MFR NDC: 0904-7192-60 Exp.: 00-00
Serial# 0000000002

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GTIN 00368071261592 Serial# 0000000002 Exp. Date 00-00

Exp. Date 00-00 LOT#: 00000

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

Product #: P1402090

WARNING: KEEP OUT OF REACH OF CHILDREN

STORE AT CONTROLLED TEMPERATURE 68-77°F.

#### **FEXOFENADINE HCL**

Rev. 01/01/19

fexofenadine hcl tablet, film coated

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68071-2615(NDC:0904-7192)

Route of Administration ORAL

#### **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength Strength

FEXOFENADINE HYDROCHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE -

UNII:E6582LOH6V)

FEXOFENADINE HYDROCHLORIDE 60 mg

## **Inactive Ingredients**

Strength

# **Product Characteristics**

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

FERRIC OXIDE YELLOW (UNII: EX43802MRT)

Color	pink	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	SG;201
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
<b>1</b> NDC:68071-2615-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/12/2022	

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA204507	08/26/2021	

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

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
NuCare Pharmaceuticals, Inc.		010632300	repack(68071-2615)	

Revised: 1/2022 NuCare Pharmaceuticals,Inc.