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

Perrigo Fexofenadine Hydrochloride Tablets, 60 mg Drug Facts

Active ingredient (in each tablet)

Fexofenadine HCI 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-

Directions

adults and children 12 years of	take one 60 mg tablet with water every 12 hours; do
age and over	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 printed foil under cap is broken or missing
- store at 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



FEXOFENADINE HYDROCHLORIDE

fexofenadine hcl tablet, film coated

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Prod	uct	ıntorr	mation

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68071-3228(NDC:45802-425)

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		
Ingredient Name	Strength	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
FERROSOFERRIC OXIDE (UNII: XM0M87F357)		
FERRIC OXIDE YELLOW (UNII: EX43802MRT)		
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POVIDONE (UNII: FZ 989GH94E)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		

Product Characteristics				
Color	orange (Peach)	Score	no score	
Shape	ROUND	Size	8mm	
Flavor		Imprint Code	93;7252	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:68071- 3228-1	10 in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2017		
2	NDC:68071- 3228-4	14 in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2017		
3	NDC:68071- 3228-2	20 in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2017		
4	NDC:68071- 3228-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2017		
5	NDC:68071- 3228-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2017		

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(68071-3228)	

Revised: 2/2021 NuCare Pharmaceuticals, Inc.