# FEXOFENADINE HYDROCHLORIDE- fexofenadine hydrochloride tablet Pioneer Life Sciences, LLC Allergy Relief Fexofenadine Hydrochlroride Tablets 180 mg **Drug Facts** Active ingredient (in each caplet) Fexofenadine HCl 180 mg **Purpose Antihistamine** Uses temporarily relieves these symptoms due to hay fever or other upper respiratory $\sqcap$ runny nose $\sqcap$ sneezing $\sqcap$ itchy, watery eyes $\sqcap$ 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 $\square$ do not take more than directed $\square$ do not take at the same time as aluminum or magnesium antacids $\square$ 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

**Directions** 

Poison Control Center (1-800-222-1222) right away.

age uo not use

adults 65 years of age and

older

ask a doctor

consumers with kidney

disease

ask a doctor

**Other information** [] store between 20° and 25°C (68° and 77°F) [] protect from excessive moisture

**Inactive ingredients:** colloidal silicone dioxide, croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol/macrogol, povidone, pregelatinized starch, red iron oxide, silica, titanium dioxide, yellow iron oxide.

#### **Questions or comments?**

Call 1 (732) 994-2808 or email support@gencare.health

This product is not manufactured or distributed by Chattem, Inc, a Sanofi Company, owner of the registered trademark Allegra® Allergy.

Distributed by: **Gencare Consumer Products, LLC** 40E Cotters Ln, Suite A, East Brunswick, NJ 08816

NDC 72090-010-03; 50s HDPE Bottle



Call 1 (732) 698-5070 Monday through Friday 9 am to 5 pm EST. or visit: www.gencare.health

Questions Or Comments?

## NDC 72090-010-04; 150s HDPE Bottle

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

Inactive Ingredients: Colloidal Silicon Dioxide, Croscamellose Sodium Hypromellose, Magnesium Stearate, Microcrystalline Cellulose,

Store between 20° to 25°C (68° to 77°F)

Other Information:

Protect from excessive moisture

Polyethylene Glycol/macrogol, Povidone, Pregelatinized Starch, Red iron oxide, Silica,

Itanium dioxide, Yellow iron oxide

**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

If pregnant or breast feeding, ask a health professional before use. KEEP OUT OF REACH OF CHILDREN. In case of overdose, get medical

Drug Facts (Cont.)

nelp or contact a Poison Control Center 1-800-222-1222) right away.

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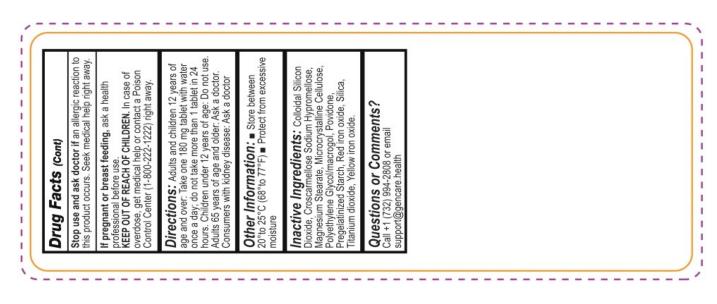
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NDC 72090-010-02; 100s HDPE Bottle



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 Directions: Adults and children 12 years of age Questions Or Comments? Call +1 (732) If pregnant or breast feeding, ask a health professional before use. KEEP OUT OF REACH OF CHILDREN. In case of overdose, get medica Croscarmellose Sodium Hypromellose Agnesium Stearate, Microcrystalline Cellulose 994-2808 or email support@gencare.health Inactive Ingredients: Colloidal Silicon Polyethylene Glycol/macrogol, Povidone, Pregelatinized Starch, Red iron oxide, Silica This product is not manufactured or distributed Store between 20° to 25°C (68° to 77°F) by Chattem, Inc, a Sanofi Company, owner of nelp or contact a Poison Control Center Protect from excessive moisture Ttanium dioxide, Yellow iron oxide with kidney disease: Ask a doctor Drug Facts (Cont.) 1-800-222-1222) right away Other Information: Dioxide,

#### **FEXOFENADINE HYDROCHLORIDE**

fexofenadine hydrochloride tablet

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# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:72090-010

Route of Administration ORAL

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength FEXOFENADINE HYDROCHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII: E6582LOH6V) FEXOFENADINE HYDROCHLORIDE 180 mg

Inactive Ingredients	
Ingredient Name	Strength
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics					
Color	orange	Score	no score		
Shape	CAPSULE	Size	17mm		
Flavor		Imprint Code			
Contains					

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:72090-010- 03	50 in 1 BOTTLE; Type 0: Not a Combination Product	10/03/2024			
2	NDC:72090-010- 04	150 in 1 BOTTLE; Type 0: Not a Combination Product	10/03/2024			
3	NDC:72090-010- 02	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/29/2024			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA210137	10/03/2024		

### **Labeler -** Pioneer Life Sciences, LLC (014092742)

## **Registrant -** Pioneer Life Sciences, LLC (014092742)

Revised: 10/2024 Pioneer Life Sciences, LLC