

FEXOFENADINE HYDROCHLORIDE- fexofenadine hydrochloride tablet
Pioneer Life Sciences, LLC

FEXOFENADINE HYDROCHLORIDE TABLETS USP 180 mg

Drug Facts

Active ingredient (in each tablet)

Fexofenadine HCl 180 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. You may report side effects to FDA at **1-800-FDA-1088**.

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

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 printed foil inner seal on bottle is torn or missing □ 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) 689-5070**

Manufactured for:

Pioneer Life Sciences, LLC

40E Suite A, Cotters Lane, East Brunswick, NJ 08816 USA

Manufactured by:

Unique Pharmaceutical Laboratories

(A Div. of J. B. Chemicals & Pharmaceuticals Ltd.)

Mumbai 400 030, India

Mfg. Lic. No.: G/1430

NDC 72090-010-99

Non-Drowsy

FEXOFENADINE HYDROCHLORIDE TABLETS USP 180 mg

antihistamine

24 Hour

indoor & outdoor allergy relief

- sneezing • runny nose
- itchy, watery eyes
- itchy nose or throat

1000 tablets

NDC XXXXX-XXX-XX

Non-Drowsy

Fexofenadine Hydrochloride Tablets USP

180 mg

**antihistamine
24 Hour**

Indoor/Outdoor Allergy Relief

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy, Nose or Throat

1,000 Tablets



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Active ingredient (in each tablet)	Purpose
Fexofenadine HCl 180 mg	Antihistamine
Uses	
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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. You may report side effects to FDA at 1-800-FDA-1088.	
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Directions	
adults and children 12 years of age and over	take one 180 mg tablet with water once a day
children under 12 years of age	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 liver or kidney disease	ask a doctor
Other information	
■ safety sealed: do not use 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	
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.	
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Pioneer Lifesciences LLC
40E suite A Cotters Lane
East Brunswick NJ 08816 USA

FOR REPACKAGING ONLY

Mfg. Lic. No.: G/1430

136917

100 mm

150 mm

FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet

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	Strength
FEXOFENADINE HYDROCHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	180 mg

Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72090-010-99	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/11/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210137	08/11/2023	

Labeler - Pioneer Life Sciences, LLC (014092742)

Revised: 8/2023

Pioneer Life Sciences, LLC