FEXOFENADINE HCL - fexofenadine hcl tablet A-S Medication Solutions

Fexofenadine Hydrochloride Tablets USP, 180 mg

ACTIVE INGREDIENT(S), in each tablet

Fexofenadine hydrochloride USP, 180 mg

PURPOSE

Antihistamine

USE(S)

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.

DIRECTIONS

60 mg

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

180 mg

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
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 carton is opened or if printed foil inner seal on the bottle is torn or missing.
- ☐ store between 20° and 25°C (68° and 77°F)
- ☐ protect from excessive moisture

INACTIVE INGREDIENTS

Colloidal silicon dioxide, hypromellose, light liquid paraffin, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, pregelatinized starch, red iron oxide, sodium starch glycolate, talc, titanium dioxide and yellow iron oxide.

QUESTIONS OR COMMENTS

call toll-free weekdays 9 AM to 5 PM EST at 1-888-588-1418

Fexofenadine HCL



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fexofenadine hcl tablet

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-4070(NDC:69230-300)		
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		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)			
LIGHT MINERAL OIL (UNII: N6K5787QVP)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
POLYSORBATE 80 (UNII: 6OZP39ZG8H)			
STARCH, CORN (UNII: O8232NY3SJ)			
FERRIC OXIDE RED (UNII: 1K09F3G675)			
FERRIC OXIDE YELLOW (UNII: EX43802MRT)			
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)			
TALC (UNII: 7SEV7J4R1U)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)			

Product Characteristics				
Color	PINK	Score	no score	
Shape	CAPSULE	Size	18mm	
Flavor		Imprint Code	J;44	
Contains				

Packaging				
# Item Code Package Description Marketing Start Marketing Date		Marketing End Date		
1	NDC:50090- 4070-1	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/18/2019	
2	NDC:50090- 4070-0	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/18/2019	
3	NDC:50090- 4070-2	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/04/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204097	08/19/2016	

Labeler - A-S Medication Solutions (830016429)

Establishment			
Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-4070), REPACK(50090-4070)

Revised: 12/2023 A-S Medication Solutions