

FEXOFENADINE HYDROCHLORIDE- fexofenadine hydrochloride tablet, film coated
AMZ789 LLC

Fexofenadine HCl Tablets USP 180 mg

ACTIVE INGREDIENT(S)

Fexofenadine HCl USP 180 mg

PURPOSE

Antihistamine

USE(S)

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- itchy, water eyes
- sneezing
- itching of the nose or throat

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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

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 (for 180 mg)
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 foil printed with granules logo under bottle cap is opened or torn.
- Do not use if carton is opened or if individual blister units are torn or opened.
- store between 20° and 25°C (68° and 77°F)
- protect from excessive moisture

Inactive Ingredients

colloidal silicon dioxide, croscarmellose sodium, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, lactose monohydrate, macrogol, magnesium stearate, microcrystalline cellulose, pregelatinized starch, titanium dioxide.

RxZell[®]

NDC 73629-008-03
Compare to the active ingredient
in ALLEGRA[®] ALLERGY 24 HOUR

Fexofenadine HCl Tablets, USP

180mg



Antihistamine

**INDOOR / OUTDOOR ALLERGY
RELIEF**

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

**30
Tablets**

FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73629-008
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
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	orange (PEACH)	Score	score with uneven pieces
Shape	OVAL	Size	12mm
Flavor		Imprint Code	G6
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73629-008-03	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/27/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211075	07/27/2024	

Labeler - AMZ789 LLC (117410213)

