SUNMARK FEXOFENADINE HYDROCHLORIDE- fexofenadine hydrochloride tablet, film coated
Strategic Sourcing Services LLC

McKesson Fexofenadine Hydrochloride Tablets, 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
- 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 (1-800-222-1222).

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
adults 65 years of age and older	ask a doctor
consumers with kidney disease	ask a doctor

Other information

- do not use if carton is opened or 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

COMPARE TO ALLEGRA® ALLERGY ACTIVE INGREDIENT

24 HR

fexofenadine hydrochloride Tablets, 180 mg/Antihistamine

Non-drowsy

Indoor/outdoor allergy relief of sneezing; runny nose; itchy, watery eyes; itchy nose or throat

ALLERGY

Actual Size

GLUTEN FREE

70 TABLETS

SUNMARK FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49348-968
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)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	ORANGE (peach)	**Score**	no score
Shape	ROUND	**Size**	12mm
Flavor		**Imprint Code**	93;7253
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-968-57	3 in 1 CARTON	04/14/2011	10/04/2017
1		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:49348-968-44	1 in 1 CARTON	04/14/2011	10/28/2018
2		30 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:49348-968-12	1 in 1 CARTON	04/14/2011	06/11/2015
3		60 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:49348-968-56	1 in 1 CARTON	04/14/2011	
4		70 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076447	04/14/2011	

Labeler - Strategic Sourcing Services LLC (116956644)

Revised: 7/2021 Strategic Sourcing Services LLC