FEXOFENADINE HYDROCHLORIDE- fexofenadine hcl tablet, film coated Rebel Distributors Corp

Perrigo Fexofenadine Hydrochloride Tablets, 60 mg Drug Facts

Active ingredient (in each tablet)

Fexofenadine HCl 60 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	take one 60 mg tablet with water every 12
of age and over	hours; do not take more than 2 tablets in 24
	hours

children under 12 years of	do not use
age	
adults 65 years of age and	ask a doctor
older	

Other information

- do not use if 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



FEXOFENADINE HYDROCHLORIDE

fexofenadine hcl tablet, film coated

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:42254-123(NDC:45802-425)

Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
FEXO FENADINE HYDRO CHLO RIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LO H6 V)	FEXOFENADINE HYDROCHLORIDE	60 mg		

Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)		
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)		
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)		
PO VIDO NE (UNII: FZ989 GH94E)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		

Product Characteristics				
Color	ORANGE (Peach)	Score	no score	
Shape	ROUND	Size	8 mm	
Flavor		Imprint Code	93;7252	
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42254-123-10	10 in 1 BOTTLE		
2	NDC:42254-123-14	14 in 1 BOTTLE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA076447	08/08/2011		

Labeler - Rebel Distributors Corp (118802834)

Establishment				
Name	Address	ID/FEI	Business Operations	
Rebel Distributors Corp		118802834	RELABEL, REPACK	

Revised: 1/2012 Rebel Distributors Corp