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

Perrigo 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	take one 180 mg tablet with water once a day; do		
years of age and over	not take more than 1 tablet in 24 hours		
children under 12 years of do not use			

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

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 hydrochloride tablet, film coated

Product	Information
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:42254-166(NDC:45802-571)

Route of Administration ORAL

Active Ingredient/Active Moiety

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Ingredient Name		Basis of Strength	Strength		
	FEXO FENADINE HYDRO CHLO RIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII: E6582LO H6 V)	FEXOFENADINE HYDROCHLORIDE	180 mg		

Inactive Ingredients

Ingredient Name
SILICON DIO XIDE (UNII: ETJ7Z6XBU4)

CROSCARMELLOSE SODIUM (UNII: M280L1HH48)

HYPROMELLOSES (UNII: 3NXW29 V3WO)

FERROSOFERRIC O XIDE (UNII: XM0 M87F357)

FERRIC O XIDE YELLOW (UNII: EX43802MRT)

LACTOSE MONOHYDRATE (UNII: EWQ57Q815X)

MAGNESIUM STEARATE (UNII: 70097M6130)

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)

POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)

PO VIDONE (UNII: FZ989GH94E)

TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)

FERRIC O XIDE RED (UNII: 15K09F3G675)

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:42254-166-30	30 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076447	04/22/2011	

Labeler - Rebel Distributors Corp (118802834)

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

Revised: 2/2012 Rebel Distributors Corp