FEXOFENADINE HYDROCHLORIDE- fexofenadine hcl tablet, film coated
Blenheim Pharmacal, Inc.

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 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	do not use

age	
adults 65 years of age and older	ask a doctor

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

Principal Display Panel

Fexofenadine Hydrochloride Tablets, 60mg

30 Tablets

NDC 10544-231-30

FEXOFENADINE HYDROCHLORIDE

fexofenadine hcl tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10544-231(NDC:45802-425)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FEXOFENADINE HYDROCHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	60 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:10544-231-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/08/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076447	11/13/2013	

Labeler - Blenheim Pharmacal, Inc. (171434587)

Registrant - Blenheim Pharmacal, Inc. (171434587)

Establishment

Name	Address	ID/FEI	Business Operations
Blenheim Pharmacal, Inc.		171434587	repack(10544-231)