

FEXOFENADINE HYDROCHLORIDE - fexofenadine hydrochloride tablet, film coated
Dispensing Solutions, Inc.

Major Pharmaceuticals 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	take one 180 mg tablet with water once a day; do not take more than
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age and over	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 blister unit is broken or torn (Use for Blister Configurations Only)
- do not use if printed foil under cap is broken or missing (Use for Bottle Configurations Only)
- 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

<p>BULK SOURCE DATA DIST. BY: MAJOR PHARMACEUTICALS LIVONIA, MI 48150 PRODUCT ID: ORANGE ROUND TABLET IMPRINTED 7253 / 93</p> <p>BULK SOURCE NDC: 00904-6214-89 MFR. LOT: XXXXXX PEDIGREE #: 20989192 DISPENSE IN THIS TIGHT/LIGHT RESISTANT CONTAINER</p> 	 FEXOFENADINE HCl 180 mg XX TABLETS NDC 66336-0561- XX PRODUCT # 808-XX EACH TABLET CONTAINS: FEXOFENADINE HYDROCHLORIDE 180 mg PURPOSE: ANTIHISTAMINE COMPARE TO ACTIVE INGREDIENT OF ALLEGRA ALLERGY TABLET LOT# SAMPLE EXP: 00-00 Rx # 25623131	<p>WARNING: KEEP OUT OF CHILDREN'S REACH STORE AT 68°- 77° F. SEE USP.</p> <p>808- XX NDC 66336-0561- XX FEXOFENADINE HCl 180 mg XX TABLETS LOT # SAMPLE EXP: 00-00 MN 00904-6214-89 RX# 25623131</p> <p>808- XX NDC 66336-0561- XX FEXOFENADINE HCl 180 mg XX TABLETS LOT # SAMPLE EXP: 00-00 MN 00904-6214-89 RX# 25623131</p> <p>808- XX NDC 66336-0561- XX FEXOFENADINE HCl 180 mg XX TABLETS LOT # SAMPLE EXP: 00-00 MN 00904-6214-89 RX# 25623131</p>  <p>Packaged Exclusively By: DISPENSING SOLUTIONS the Santa Ana, CA 92704</p>
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NDC 66336-0561-XX
NDC 66336-0561-30

COMPARE TO active ingredient of ALLEGRA® ALLERGY TABLETS

Original Prescription Strength

FEXOFENADINE HYDROCHLORIDE TABLETS, 180 mg

Antihistamine
ALLERGY

Relief of:

Sneezing

Runny Nose

Itchy, Watery Eyes

Itchy Nose or Throat

Indoor and Outdoor Allergies

24 HOUR

Non-Drowsy

actual size

180 mg EACH

FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66336-561(NDC:0904-6214)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FEXO FENADINE HYDRO CHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	180 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIO XIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	

POVIDONE (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:66336-561-30	30 in 1 BOTTLE		

Marketing Information

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

Labeler - Dispensing Solutions, Inc. (066070785)

Registrant - PSS World Medical, Inc. (101822682)

Establishment

Name	Address	ID/FEI	Business Operations
Dispensing Solutions, Inc.		066070785	relabel, repack

Revised: 2/2012

Dispensing Solutions, Inc.