FEXOFENADINE HYDROCHLORIDE - fexofenadine hydrochloride tablet Physicians Total Care, Inc.

Fexofenadine HCl Tablets USP

Active ingredient(s)

Fexofenadine HCl USP, 180 mg

Purpose

Antihistamine

Use(s)

temporarily relieves these symptoms due to hay fever or otherupper respiratory allergies:

- runny nose
- itchy, watery eys
- sneezing
- itching of the nose or Throad

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 doctorshould 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 doctor if

Allergy

an allergic reaction to this product occurs. Seek medical help right away.

Pregnancy/Breastfeeding

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.

Directions

adults and children 12 years of age	take one 180 mg tablet with water once a day; do not take more
and over	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

safety sealed: do not use if carton is opened or if individual blister units are torn or opened.

Storage

store between 20° - 25°C (68° - 77°F) protect from excessive moisture

Inactive ingredients

colloidal silicon dioxide, corn starch, croscarmellose sodium, magnesium stearate, mannitol, and powdered cellulose, opadry pink 03B54504 containing FD&C Red no. 40, hypromellose, iron oxide black, polyethylene glycol and titanium dioxide.

Questions

call toll-free 1-888-375-3784

Manufactured by:

Dr. Reddy's Laboratories Louisiana LLC,

8800 Line Ave Shreveport, LA, 71106.

OR

Manufactured by:

Dr. Reddy's Laboratories Limited

Bachepalli - 502 325 INDIA

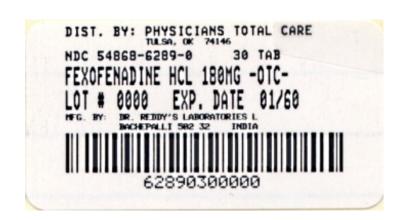
Additional barcode labeling by:

Physicians Total Care, Inc. Tulsa, OK 74146

Principal Display Panel

Fexofenadine HCl USP, 180 mg

NDC 54868-6289-0



FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:54868-6289(NDC:55111-784)

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 DIO XIDE (UNII: ETJ7Z6 XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)	
magnesium stearate (UNII: 70097M6I30)	
mannitol (UNII: 3OWL53L36A)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
FERRIC OXIDE BLACK (UNII: XM0 M87F357)	
polyethylene glycol 400 (UNII: B697894SGQ)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics					
Color	PINK	Score	no score		
Shape	OVAL	Size	7mm		
Flavor		Imprint Code	194;R		
Contains					

Packaging

#	Item Code	Package Description	Marketii	ng Start Date	M	arketing End Date
1	NDC:54868-6289-0	30 in 1 BOTTLE				
2	NDC:54868-6289-1	90 in 1 BOTTLE				
Marketing Information						
N	Sarketing Category A	pplication Number or Monogra	ph Citation	Marketing Start	Date	Marketing End Date

 $0\,7/27/20\,11$

Labeler - Physicians Total Care, Inc. (194123980)

ANDA076502

ANDA

Establishment					
Name	Address	ID/FEI	Business Operations		
Physicians Total Care, Inc.		194123980	relabel, repack		

Revised: 4/2011 Physicians Total Care, Inc.