FEXOFENADINE HYDROCHLORIDE- fexofenadine hydrochloride tablet
Chain Drug Consortium, LLC

Fexofenadine HCl Tablets USP

Active ingredient(s)

Fexofenadine HCl USP, 180 mg

Purpose

Antihistamine

Use(s)

Allergy

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

- runny nose
- itchy, watery eyes
- sneezing
- itching of the nose or throat

Hives

reduces hives and relieves itching due to hives (urticaria). This product will not prevent hives or an allergic skin reaction from occuring.

Warnings

Hives

Severe Allergic Warning: Get emergency help **immediately** if you have hives along with any of the following symptom:

- trouble swallowing
- dizziness or loss of consciousness
- swelling of tongue
- swelling in or around mouth
- trouble speaking
- drooling
- wheezing or problems breathing

These symptoms may be signs of anaphylactic shock. This condition canbe life threatening if not treated by a health professional **immediately**.Symptoms of

anaphylactic shock may occur when hives first appear or upto a few hours later.

Not a Substitute for Epinephrine. If your doctor has prescribed an epinephrineinjector for “anaphylaxis” or severe allergy symptoms that could occur withyour hives, never use this product as a substitute for the epinephrine injector.If you have been prescribed an epinephrine injector, you should carry it withyou at all times.

Do not use

Allergy

if you have ever had an allergic reaction to this product or any of its ingredients.

Hives

- to **prevent** hives from any known cause such as:
  - foods
  - insect stings
  - medicines
  - latex or rubber gloves

because this product will not stop hives from occurring. Avoiding the cause of your hives is the only way to prevent them. Hives can sometimes be serious. If you do not know the cause of your hives, see your doctor for a medical exam. Your doctor may be able to help you find a cause.

- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

Allergy

- kidney disease. Your doctorshould determine if you need a different dose.

Hives

- kidney disease. Your doctor should determine if you need a different dose.
- hives that are an unusual color, look bruised or blistered
- hives that do not itch

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.

Hives

- an allergic reaction to this product occurs. Seek medical help right away.
- symptoms do not improve after 3 days of treatment
- the hives have lasted more than 6 weeks

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.

Directions

180 mg

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

this product meets the requirements of USP Dissolution Test 2.

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 or comments?

call toll-free **1-888-375-3784**

Manufactured by:

Dr. Reddy’s Laboratories Limited

Bachupally - 500 090 INDIA

containercarton

Container Carton Label: 30 count

FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-995(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 DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
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)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

polyethylene glycol 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
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	Marketing Start Date	Marketing End Date
1	NDC:68016-995-03	1 in 1 CARTON	04/01/2014	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:68016-995-45	1 in 1 CARTON	04/01/2014	
2		45 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076502	04/01/2014	

Labeler - Chain Drug Consortium, LLC (101668460)

Revised: 1/2014 Chain Drug Consortium, LLC