FEXOFENADINE HCL- fexofenadine hcl tablet
GRANULES PHARMACEUTICALS INC.

Fexofenadine HCL Tablets, USP 180mg
Antihistamine
Indoor/Outdoor Allergy Relief

Active ingredient (in each tablet)

Fexofenadine HCl USP, 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

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

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.

Directions

adults and children 12 years of age and over take one 180mg 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 imprinted foil under bottle cap is opened or torn.
■store between 20° and 25°C (68° and 77°F)
■protect from excessive moisture

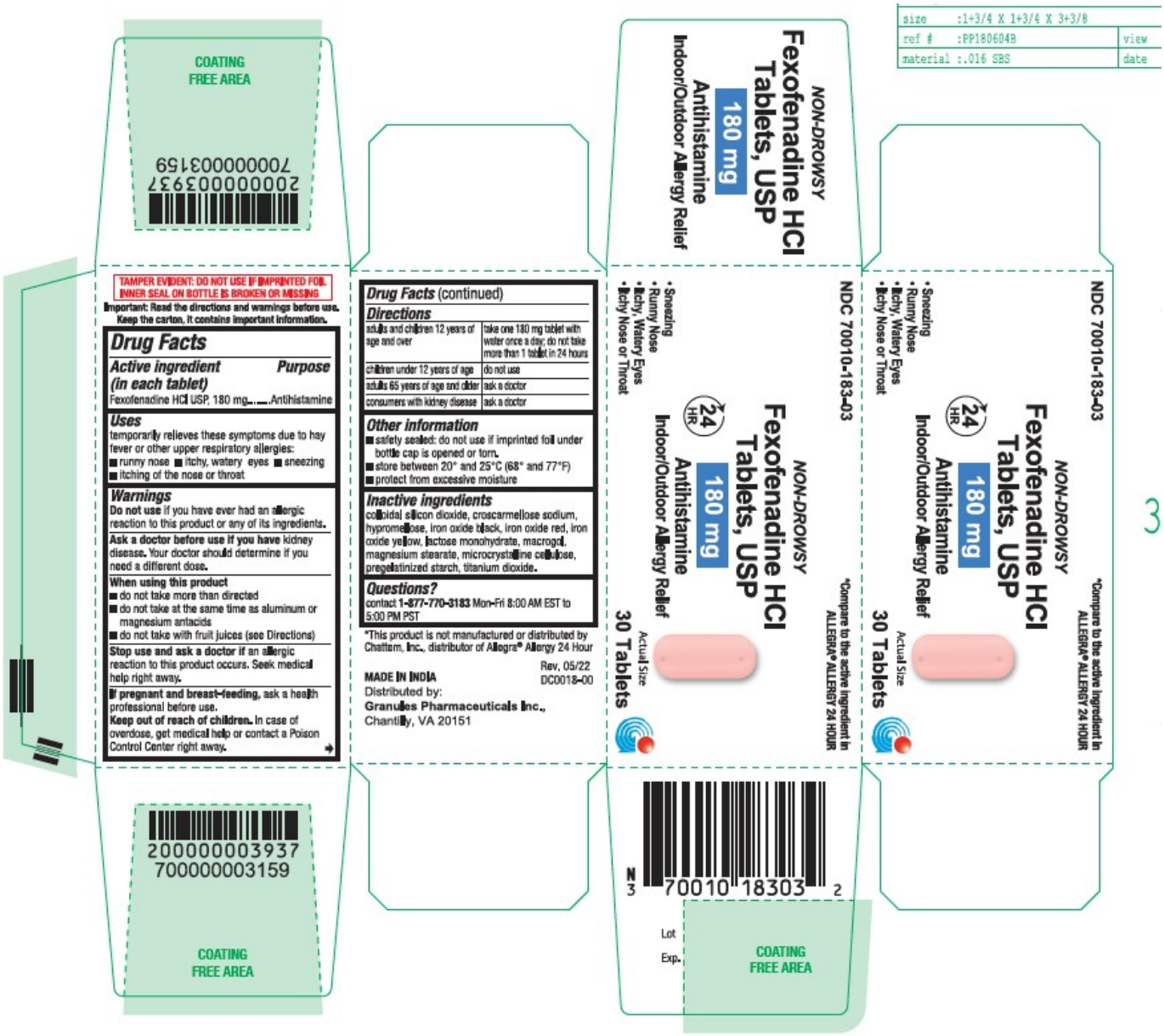
Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, lactose monohydrate, macrogol, magnesium stearate, microcrystalline cellulose, pregelatinized starch, titanium dioxide.

Questions or comments?

call 1-877-770-3183 Mon-Fri 8:00 AM EST to 5:00 PM PST.

Principal Display Panel



FEXOFENADINE HCL

fexofenadine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70010-183
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
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange (peach)	**Score**	no score
Shape	OVAL	**Size**	17mm
Flavor		**Imprint Code**	G6
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70010-183-03	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/25/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211075	04/25/2023	

Labeler - GRANULES PHARMACEUTICALS INC. (079825711)

Revised: 4/2023 GRANULES PHARMACEUTICALS INC.