FEXOFENADINE HYDROCHLORIDE - fexofenadine hydrochloride tablet, film coated
Sun Pharmaceutical Industries, Inc.

Fexofenadine Hydrochloride Tablets, USP

Active ingredient (in each tablet)

For 180 mg:
Fexofenadine HCl, USP 180 mg

Purpose

Antihistamine

Uses

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

Warnings

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

- 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 can be life threatening if not treated by a health professional **immediately.** Symptoms of anaphylactic shock may occur when hives first appear or up to a few hours later.

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

Do not use

- 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

- 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

- 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

For 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 inner safety seal is open or torn
- store between 20° to 25°C (68° to 77°F)
- protect from excessive moisture

Inactive ingredients

croscarmellose sodium, hypromellose, iron oxide red, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized maize starch, titanium dioxide

Questions?

Call toll free **1-800-818-4555** weekdays.

Principal Display Panel

For 180 mg : Label

NDC 62756-545-15

Fexofenadine Hydrochloride Tablets, USP

180 mg

HIVES

(24 Hour)

Reduces HIVES and Relieves ITCHING due to hives

Antihistamine

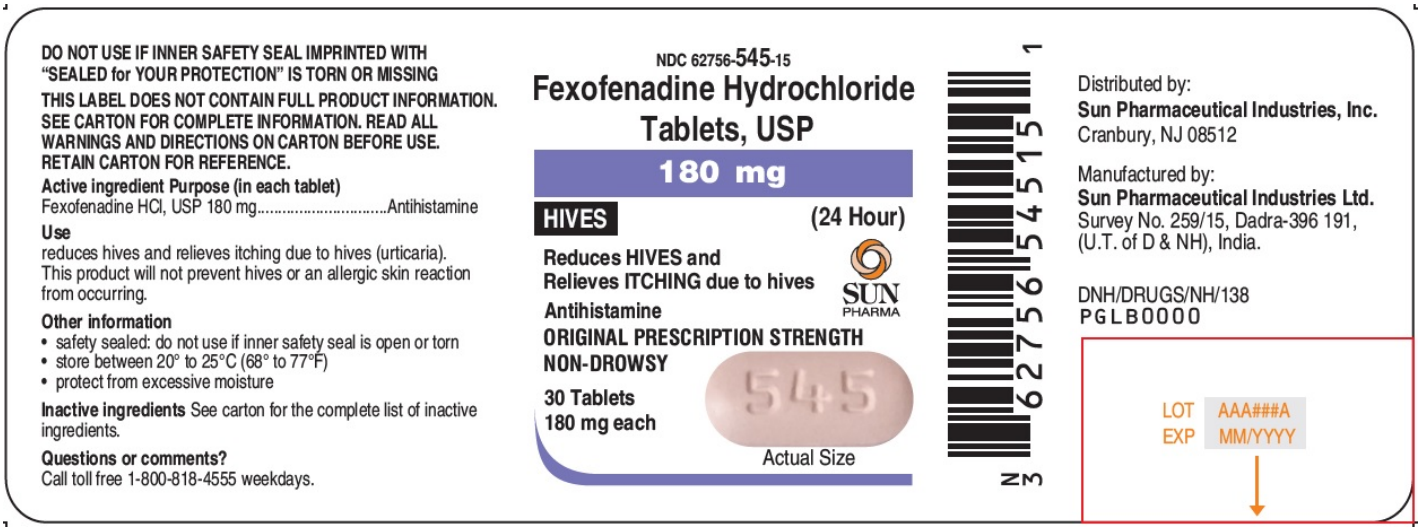
ORIGINAL PRESCRIPTION STRENGTH

NON-DROWSY

30 Tablets

180 mg each

Actual Size



Principal Display Panel

For 180 mg : Carton

NDC 62756-545-15

Fexofenadine Hydrochloride Tablets, USP

180 mg

HIVES

(24 Hour)

Reduces HIVES and Relieves ITCHING due to hives

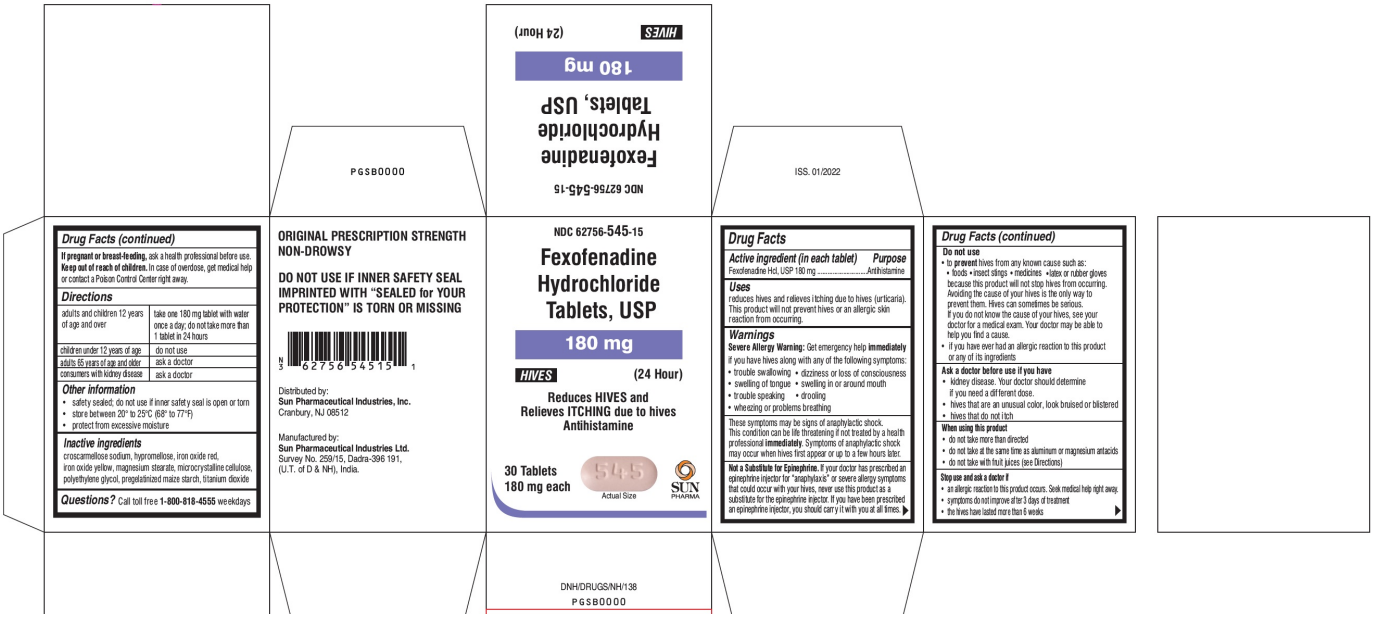
Antihistamine

NON-DROWSY

30 Tablets

180 mg each

Actual Size



Principal Display Panel

For 180 mg : Blister Pack

NDC 62756-545-15

ORIGINAL PRESCRIPTION STRENGTH

NON-DROWSY

Fexofenadine Hydrochloride Tablets, USP

180 mg

HIVES

(24 Hour)

Reduces HIVES and Relieves ITCHING due to hives

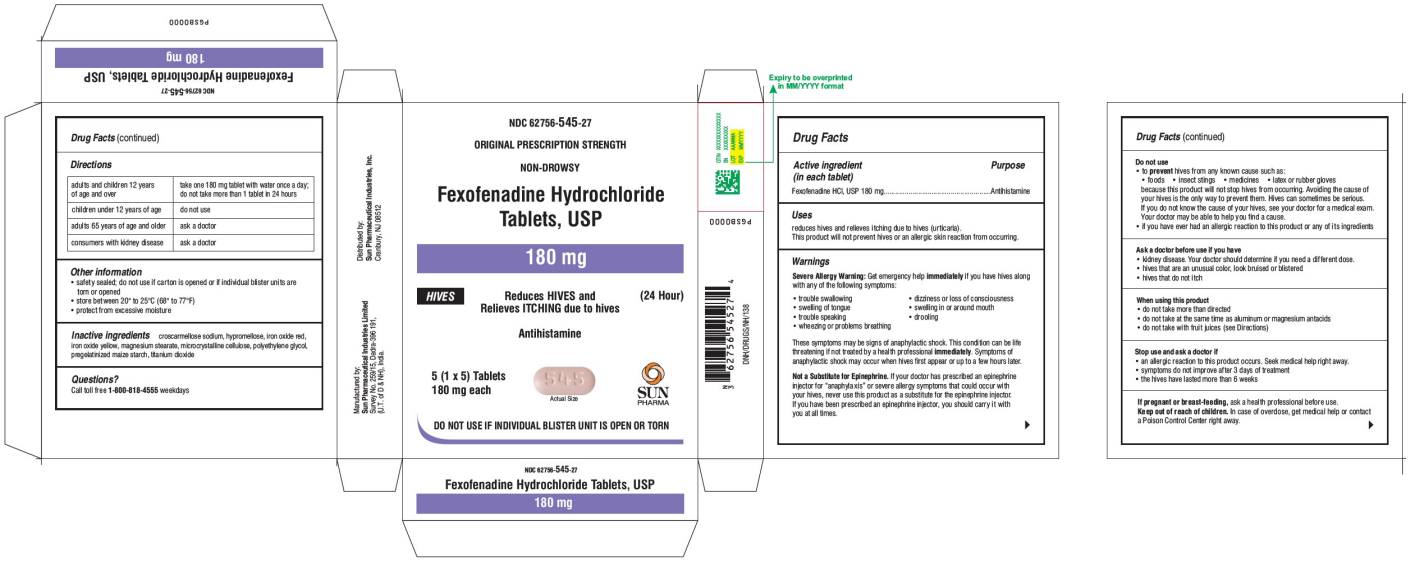
Antihistamine

5 (1 x 5) Tablets

180 mg each

Actual Size

DO NOT USE IF INDIVIDUAL BLISTER UNIT IS OPEN OR TORN



Principal Display Panel

For 180 mg : Blister Foil

Fexofenadine Hydrochloride Tablets, USP

24 Hour

180 mg

HIVES

Antihistamine

Mfg. by: Sun Pharmaceutical Ind. Ltd., India.

FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62756-545
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)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	PINK	**Score**	no score
Shape	CAPSULE	**Size**	17mm
Flavor		**Imprint Code**	545
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62756-545-27	1 in 1 CARTON	06/30/2022	
1	NDC:62756-545-31	5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:62756-545-94	2 in 1 CARTON	06/30/2022	
2	NDC:62756-545-31	5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:62756-545-25	3 in 1 CARTON	06/30/2022	
3	NDC:62756-545-31	5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:62756-545-15	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2022	
5	NDC:62756-545-17	45 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2022	
6	NDC:62756-545-18	70 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2022	
7	NDC:62756-545-19	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2022	
8	NDC:62756-545-20	150 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2022	
9	NDC:62756-545-21	180 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2022	
10	NDC:62756-545-22	300 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091567	06/30/2022	

Labeler - Sun Pharmaceutical Industries, Inc. (146974886)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries Limited		650445203	ANALYSIS(62756-545) , MANUFACTURE(62756-545)

Revised: 6/2022 Sun Pharmaceutical Industries, Inc.