FEXOFENADINE HYDROCHLORIDE- fexofenadine hydrochloride tablet
MAJOR PHARMACEUTICALS

Fexofenadine HCl Tablets USP

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

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 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.

Directions

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 printed foil inner seal on bottle is torn or missing
- store between 20° and 25°C (68° and 77°F)
- protect from excessive moisture
- this product meets the requirements of USP Dissolution Test 4

Inactive ingredients

colloidal silicon dioxide, corn starch, croscarmellose sodium, FD&C Red no. 40, hypromellose, iron oxide black, magnesium stearate, mannitol, polyethylene glycol, powder cellulose and titantium dioxide

Questions?

call **1-888-375-3784**

Package Label - 30 Count Carton

MAJOR

COMPARE TO active ingredient of
ALLEGRA® ALLERGY 24 HOUR TABLETS*

NDC 0904-6711-46

Original Prescription Strength

FEXOFENADINE
HYDROCHLORIDE Tablets USP, 180 mg
Antihistamine

ALLERGY

Relief of:

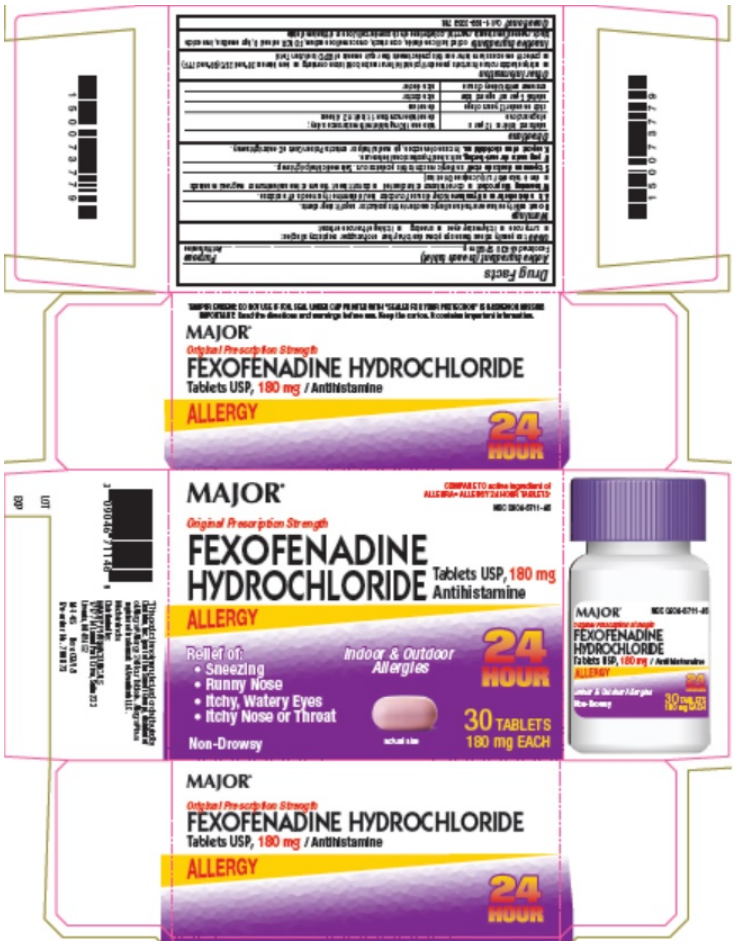
- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Nose or Throat

Non-Drowsy

Indoor & Outdoor Allergies

24 HOUR

30 TABLETS
180 mg EACH



Package Label - 30 Count Bottle

MAJOR NDC 0904-6711-46

Original Prescription Strength

FEXOFENADINE HYDROCHLORIDE
Tablets USP, 180 mg / Antihistamine

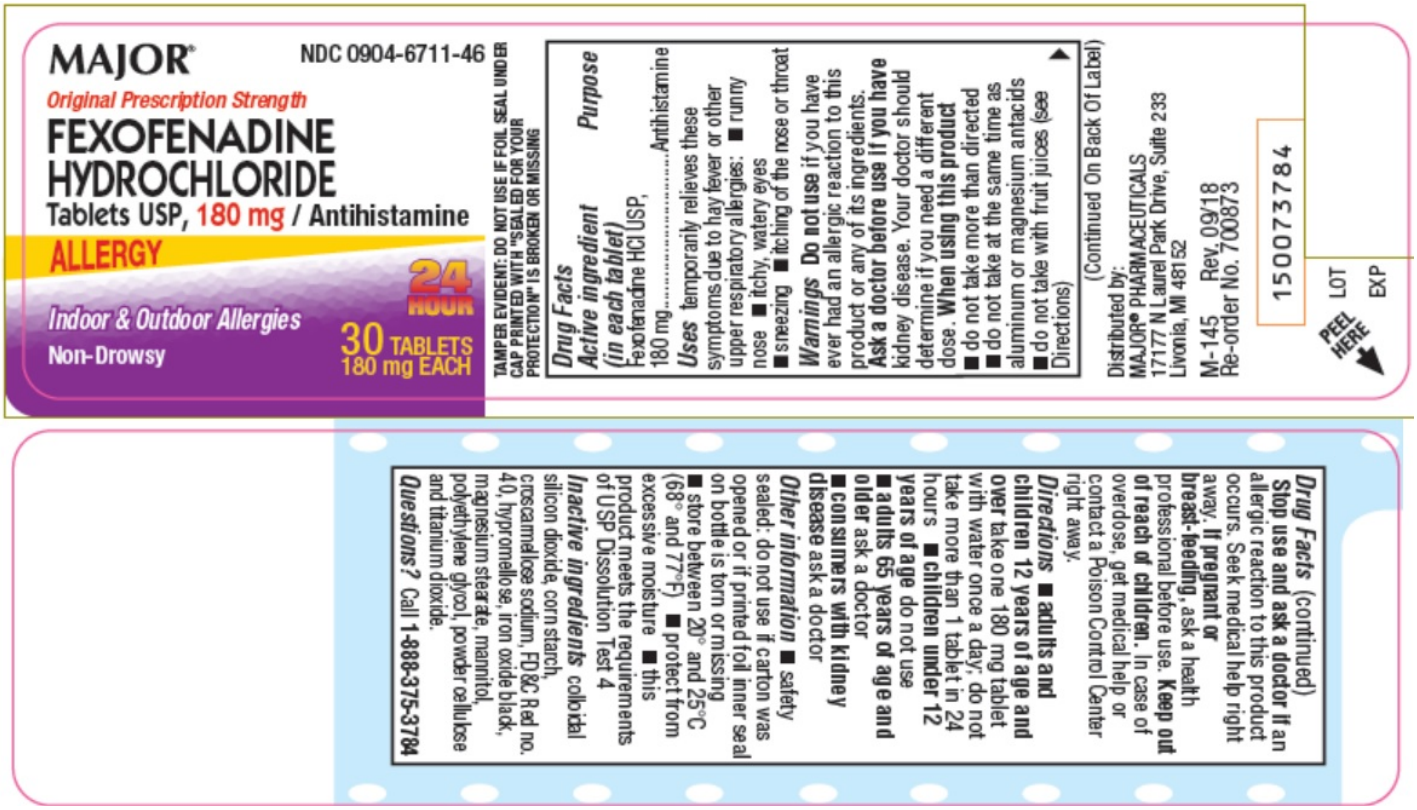
ALLERGY

Indoor & Outdoor Allergies

Non-Drowsy

24
HOUR

30 TABLETS
180 mg EACH



FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0904-6711(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:0904-6711-46	1 in 1 CARTON	04/27/2018	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0904-6711-52	2 in 1 CARTON	04/27/2018	
2		30 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0904-6711-10	3 in 1 CARTON	04/27/2018	
3		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:0904-6711-89	1 in 1 CARTON	04/27/2018	
4		90 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:0904-6711-92	1 in 1 CARTON	04/27/2018	
5		150 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	04/27/2018	

Labeler - MAJOR PHARMACEUTICALS (191427277)

Revised: 3/2018 MAJOR PHARMACEUTICALS