

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 titanium 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

MAJOR® NDC 0904-6711-46

Original Prescription Strength

**FEXOFENADINE
HYDROCHLORIDE**

Tablets USP, 180 mg / Antihistamine

ALLERGY

Indoor & Outdoor Allergies

Non-Drowsy

TAMPER EVIDENT: DO NOT USE IF FOIL SEAL UNDER CAP PRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING

24 HOUR

**30 TABLETS
180 mg EACH**

Drug Facts

Active ingredient
(in each tablet)
Fexofenadine HCl USP,
180 mg.....Antihistamine

Purpose
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)

(Continued On Back Of Label)

Distributed by:
MAJOR® PHARMACEUTICALS
17177 N Laurel Park Drive, Suite 233
Livonia, MI 48152

M-145 Rev. 09/18
Re-order No. 700873

150073784

LOT
EXP

PEEL
HERE

Drug Facts (continued)

Stop use and ask a 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 was 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 titanium dioxide.

Questions? Call 1-888-375-3784

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)	
CROSCARMELOSE 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)	
FERROSO FERRIC 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	08/31/2026
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0904-6711-52	2 in 1 CARTON	04/27/2018	10/30/2022
2		30 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0904-6711-10	3 in 1 CARTON	04/27/2018	10/30/2022
3		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:0904-6711-89	1 in 1 CARTON	04/27/2018	10/30/2022
4		90 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:0904-6711-92	1 in 1 CARTON	04/27/2018	10/30/2022
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	08/31/2026

Labeler - MAJOR PHARMACEUTICALS (191427277)

Revised: 7/2025

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