FEXOFENADINE HYDROCHLORIDE- fexofenadine hydrochloride tablet, film coated
HARMON STORES INC.

Original Prescription Strength
Allergy Relief
Fexofenadine Hydrochloride Tablets, USP
180mg/Antihistamine
NON-DROWSY
Indoor & Outdoor Allergies

Active ingredient

(in each film-coated tablet)

Fexofenadine HCl USP, 180 mg

Purpose

Antihistamine

Uses

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

■ runny nose

■ sneezing

■ itchy, watery eyes

■ 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 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 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

■ store between 20° and 25°C (68° and 77°F)

■ protect from excessive moisture

■ **each tablet contains:** sodium 8.2 mg

■ this product meets the requirements of USP Dissolution Test 2

Inactive ingredients

anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, lactose monohydrate, polyethylene glycol, pregelatinized starch (maize), red iron oxide, stearic acid, titanium dioxide and yellow iron oxide.

Questions?

call **1-877-770-3183** Mon-Fri 9:00 AM to 4:30 PM EST.

code # :
size :1+3/4 X 1+3/4 X 3+3/8
ref # :PP1806043
material :.016 SBS

CORE VALUES™

Original Prescription Strength

Allergy Relief

Fexofenadine Hydrochloride Tablets, USP

180 mg / Antihistamine

24 HOUR NON-DROWSY

30 TABLETS

CORE VALUES™

Compare to active ingredient in Allegra® Allergy 24 Hour Tablets*

Original Prescription Strength

Allergy Relief

Fexofenadine Hydrochloride Tablets, USP

180 mg / Antihistamine

Indoor & Outdoor Allergies

24 HOUR

Relief of:

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

30 TABLETS

Actual Size

NON-DROWSY

Drug Facts (continued)

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

- store between 20° and 25°C (68° and 77°F)
- protect from excessive moisture
- each tablet contains: sodium 8.2 mg
- this product meets the requirements of *USP Dissolution Test 2*

Inactive ingredients

anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, lactose monohydrate, polyethylene glycol, pregelatinized starch (maize), red iron oxide, stearic acid, titanium dioxide and yellow iron oxide.

Questions?

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Made in India

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Purpose! Do not use if imprinted inner safety seal is torn or missing.

Important: Read the directions and warnings before use. Keep the carton, it contains important information.

Drug Facts

Active ingredient (In each film-coated tablet) — **Purpose**

Fexofenadine HCl USP, 180 mg ..... Antihistamine

Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ runny nose ■ sneezing ■ itchy, watery eyes ■ 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 a doctor if an allergic reaction to this product occurs. Seek medical help right away.

If pregnant and 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.

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Lot

Exp.

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COATING FREE AREA

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FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63940-769
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
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	pink	**Score**	no score
Shape	OVAL (Capsule Shaped Tablets)	**Size**	17mm
Flavor		**Imprint Code**	SG;202
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63940-769-03	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2018	
2	NDC:63940-769-70	70 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204507	10/01/2018	

Labeler - HARMON STORES INC. (804085293)

Revised: 12/2019 HARMON STORES INC.