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

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

Active ingredient

(in each film-coated tablet)

Fexofenadine HCl USP, 60 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 60 mg tablet with water every 12 hours; do not take more than 2 tablets 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 2.7 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.

FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63940-768
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FEXOFENADINE HYDROCHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	60 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 (modified oval shaped tablets)	**Size**	12mm
Flavor		**Imprint Code**	SG;201
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63940-768-24	24 in 1 BLISTER PACK; Type 0: Not a Combination Product	11/15/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204507	11/15/2018	

Labeler - HARMON STORES INC. (804085293)

Revised: 12/2019 HARMON STORES INC.