FEXOFENADINE HCL- fexofenadine hcl tablet, film coated
Major Pharmaceuticals

ALLERGY

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 (1-800-222-1222).

Directions

adults and children 12 years of age and over	take one 60mg 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 2.7mg(for 60 mg)

- this product meets the requirements of USP *Dissolution Test 2*

Inactive ingredients

anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, lactose monohydrate, pregelatinized starch(maize), stearic acid, opadry pink 03B84893 containing hypromellose, polyethylene glycol, red iron oxide titanium dioxide and yellow iron oxide.

Questions or comments?

Call toll-free **1-800-616-2471**

Distributed by:

MAJOR ®PHARMACEUTICALS

Indianapolis, IN 46268

Package/Label Principal Display Panel

MAJOR ®

NDC 0904-7192-60

Compare to the active ingredient in Allegra ®Allergy *

Non-Drowsy

Fexofenadine Hydrochloride Tablets USP

60 mg

Antihistamine

12 HR

Indoor/Outdoor Allergy Relief

• Sneezing • Runny Nose

• Itchy, Watery Eyes • Itchy Nose or Throat

100 Tablets Allergy

MAJOR ®

NDC 0904-7192-40

Compare to the active ingredient in Allegra ®Allergy *

Non-Drowsy

Fexofenadine Hydrochloride Tablets USP

60 mg

Antihistamine

12 HR

Indoor/Outdoor Allergy Relief

• Sneezing • Runny Nose

• Itchy, Watery Eyes • Itchy Nose or Throat

500 Tablets Allergy

FEXOFENADINE HCL

fexofenadine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0904-7192
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
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	pink	**Score**	no score
Shape	OVAL	**Size**	12mm
Flavor		**Imprint Code**	SG;201
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-7192-60	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/26/2021	
2	NDC:0904-7192-40	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/26/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204507	08/26/2021	

Labeler - Major Pharmaceuticals (191427277)

Registrant - ScieGen Pharmaceuticals, Inc. (079391286)

Establishment

Name	Address	ID/FEI	Business Operations
ScieGen Pharmaceuticals, Inc.		079391286	analysis(0904-7192) , manufacture(0904-7192) , pack(0904-7192) , label(0904-7192)