

FEXOFENADINE HCL- fexofenadine hcl tablet, film coated
A-S Medication Solutions

FEXOFENADINE HYDROCHLORIDE TABLETS USP, 180 mg
Allergy

ALLERGY

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
- 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 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

- 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
- 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, 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 1-888-588-1418

Distributed by:

Camber Consumer Care, Inc.

Piscataway, NJ 08854, USA,

Made in USA

HOW SUPPLIED

Product: 50090-2457

NDC: 50090-2457-0 30 TABLET, FILM COATED in a BOTTLE

NDC: 50090-2457-1 90 TABLET, FILM COATED in a BOTTLE

Fexofenadine HCl



FEXOFENADINE HCL

fexofenadine hcl tablet, film coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|-------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50090-2457(NDC:69230-202) |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|----------------------------|----------|
| FEXO FENADINE HYDRO CHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V) | FEXOFENADINE HYDROCHLORIDE | 180 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ANHYDRO US LACTOSE (UNII: 3SY5LH9PMK) | |
| SILICON DIO XIDE (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 DIO XIDE (UNII: 15FIX9V2JP) | |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | |

Product Characteristics

| | | | |
|-----------------|---------|---------------------|----------|
| Color | pink | Score | no score |
| Shape | CAPSULE | Size | 17mm |
| Flavor | | Imprint Code | SG;202 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:50090-2457-0 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 08/24/2016 | |
| 2 | NDC:50090-2457-1 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 08/12/2016 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA204507 | 09/16/2015 | |

Labeler - A-S Medication Solutions (830016429)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|--|
| A-S Medication Solutions | | 830016429 | RELABEL(50090-2457) , REPACK(50090-2457) |

Revised: 1/2020

A-S Medication Solutions