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

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### Perrigo Fexofenadine Hydrochloride Tablets, 60 mg Drug Facts

#### Active ingredient (in each tablet)

Fexofenadine HCI 60 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 (1-800-222-1222).

#### **Directions**

| adults and children 12 years of  | take one 60 mg tablet with water every 12 hours; do |
|----------------------------------|---|
| age and over                     | 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

- do not use if carton is opened or printed foil under cap is broken or missing
- store between 20°-25°C (68°-77°F)
- protect from excessive moisture
- this product meets the requirements of USP Dissolution Test 3

### **Inactive ingredients**

colloidal silicon dioxide, croscarmellose sodium, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, titanium dioxide

#### Questions or comments?

1-800-719-9260

#### **HOW SUPPLIED**

Product: 50090-0950

NDC: 50090-0950-1 30 TABLET, FILM COATED in a BOTTLE

NDC: 50090-0950-0 10 TABLET, FILM COATED in a BOTTLE

#### Fexofenadine HCI



### **FEXOFENADINE HYDROCHLORIDE**

fexofenadine hcl tablet, film coated

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:50090-0950(NDC:45802-425)

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
FEXOFENADINE HYDROCHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII: E6582LOH6V)

FEXOFENADINE HYDROCHLORIDE

FEXOFENADINE HYDROCHLORIDE

60 mg

| Inactive Ingredients                                |          |  |  |
|---|----------|--|--|
| Ingredient Name                                     | Strength |  |  |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                  |          |  |  |
| CROSCARMELLOSE SODIUM (UNII: M280L1HH48)            |          |  |  |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)        |          |  |  |
| FERROSOFERRIC OXIDE (UNII: XM0M87F357)              |          |  |  |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                 |          |  |  |
| FERRIC OXIDE YELLOW (UNII: EX43802MRT)              |          |  |  |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)              |          |  |  |
| MAGNESIUM STEARATE (UNII: 70097M6I30)               |          |  |  |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)       |          |  |  |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) |          |  |  |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)            |          |  |  |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                 |          |  |  |

| Product Characteristics |                |       |          |
|-------------------------|----------------|-------|----------|
| Color                   | ORANGE (Peach) | Score | no score |
| Shape                   | ROUND          | Size  | 8mm      |

| Flavor   | Imprint Code | 93;7252 |
|----------|--------------|---------|
| Contains |              |         |

| Packaging |                      |   |                         |                       |
|-----------|----------------------|---|-------------------------|-----------------------|
| #         | Item Code            | Package Description                               | Marketing Start<br>Date | Marketing End<br>Date |
| 1         | NDC:50090-<br>0950-1 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 11/28/2014              |                       |
| 2         | NDC:50090-<br>0950-0 | 10 in 1 BOTTLE; Type 0: Not a Combination Product | 12/07/2018              |                       |

| Marketing Information |   |                         |                       |
|-----------------------|---|-------------------------|-----------------------|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| ANDA                  | ANDA076447                                  | 08/08/2011              |                       |
|                       |   |                         |                       |

## Labeler - A-S Medication Solutions (830016429)

| Establishment            |         |           |   |
|--------------------------|---------|-----------|---|
| Name                     | Address | ID/FEI    | Business Operations                     |
| A-S Medication Solutions |         | 830016429 | RELABEL(50090-0950), REPACK(50090-0950) |

Revised: 6/2021 A-S Medication Solutions