

FEXOFENADINE HYDROCHLORIDE- fexofenadine hydrochloride 60 mg tablet
Kroger Company

Omeprazole Delayed Release Tablets

Active ingredient(s)

Fexofenadine HCl USP, 60 mg

Purpose

Antihistamine

Use(s)

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 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

- safety sealed: do not use if carton is opened or if individual blister units are torn or opened
- store between 20° and 25°C (68° and 77°F)
- protect from excessive moisture
- this product meets the requirements of USP Dissolution Test 4

Inactive ingredients

colloidal silicon dioxide, corn starch, croscarmellose sodium, FD&C Red no. 40, hypromellose, iron oxide black, magnesium stearate, mannitol, polyethylene glycol, powder cellulose and titanium dioxide

Questions?

Call **1-888-375-3784**

PACKAGE LABEL PRINCIPAL DISPLAY PANEL SECTION



FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride 60 mg tablet

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:30142-091(NDC:55111-783) |
| 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 |
|---|----------|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) | |
| magnesium stearate (UNII: 70097M6I30) | |

| | |
|---|--|
| mannitol (UNII: 3OWL53L36A) | |
| POWDERED CELLULOSE (UNII: SMD1X3XO9M) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6) | |
| FERROSFERRIC OXIDE (UNII: XM0M87F357) | |
| polyethylene glycol 400 (UNII: B697894SGQ) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |

Product Characteristics

| | | | |
|-----------------|------|---------------------|----------|
| Color | PINK | Score | no score |
| Shape | OVAL | Size | 5mm |
| Flavor | | Imprint Code | 193;R |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:30142-091-12 | 2 in 1 CARTON | 01/03/2022 | |
| 1 | | 6 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA076502 | 01/03/2022 | |

Labeler - Kroger Company (006999528)