**FEXOFENADINE HYDROCHLORIDE- fexofenadine hydrochloride tablet, film coated**
**OHM LABORATORIES INC.**

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**Fexofenadine Hydrochloride Tablets, USP 180 mg**

***Drug Facts***

**Active ingredient (in each 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 (1-800-222-1222).

**Directions**

| | |
|---|---|
| adults and children 12 years of age and over | take one 180 mg 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 inner safety seal is torn or missing
- store between 20° to 25°C (68° to 77°F)
- protect from excessive moisture

**Inactive ingredients**

croscarmellose sodium, hypromellose, iron oxide red, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized maize starch, titanium dioxide

**Questions or comments?**

Call toll-free weekdays 8:30 AM to 5 PM EST at **1-800-818-4555**.

Distributed by:
**Ohm Laboratories Inc.**
New Brunswick, NJ 08901
MADE IN INDIA

**PRINCIPAL DISPLAY PANEL - 180 mg Tablet Bottle Carton**

†Compare To
the active ingredient of
Allegra® Allergy

NDC 51660-998-30

NDC 51660-998-55

NON-DROWSY

Fexofenadine Hydrochloride
Tablets, USP 180 mg

Antihistamine

Indoor and Outdoor Allergies

ALLERGY

24 Hour
Relief of:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Nose or Throat

ohm®

30 Tablets

DO NOT USE IF INNER SAFETY SEAL IMPRINTED WITH
"SEALED for YOUR PROTECTION" IS TORN OR MISSING


## FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet, film coated

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:51660-998 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **FEXOFENADINE HYDROCHLORIDE** (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V) | FEXOFENADINE HYDROCHLORIDE | 180 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **POLYETHYLENE GLYCOL 400** (UNII: B697894SGQ) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **FERRIC OXIDE YELLOW** (UNII: EX438O2MRT) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | PINK | **Score** | no score |
| **Shape** | OVAL | **Size** | 17mm |
| **Flavor** | | **Imprint Code** | 545 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:51660-998-30 | 1 in 1 CARTON | 04/29/2022 | |
| **1** | | 30 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **2** | NDC:51660-998-55 | 1 in 1 CARTON | 04/29/2022 | |
| **2** | | 150 in 1 BOTTLE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA091567 | 04/29/2022 | |

## Labeler - OHM LABORATORIES INC. (184769029)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Sun Pharmaceutical Industries Limited | | 650445203 | MANUFACTURE(51660-998) |