**FEXOFENADINE HCL- fexofenadine hcl tablet**
**Northwind Pharmaceuticals, LLC**

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**Fexofenadine Hydrochloride Tablets USP, 180 mg**

**ACTIVE INGREDIENT(S), in each tablet**

Fexofenadine hydrochloride USP, 180 mg

**PURPOSE**

Antihistamine

**USE(S)**

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.

**DIRECTIONS**

60 mg

| | |
|---|---|
| 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 |

180 mg

| | |
|---|---|
| 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 printed foil inner seal on the bottle is torn or missing.
- □ store between 20° and 25°C (68° and 77°F)
- □ protect from excessive moisture

**INACTIVE INGREDIENTS**

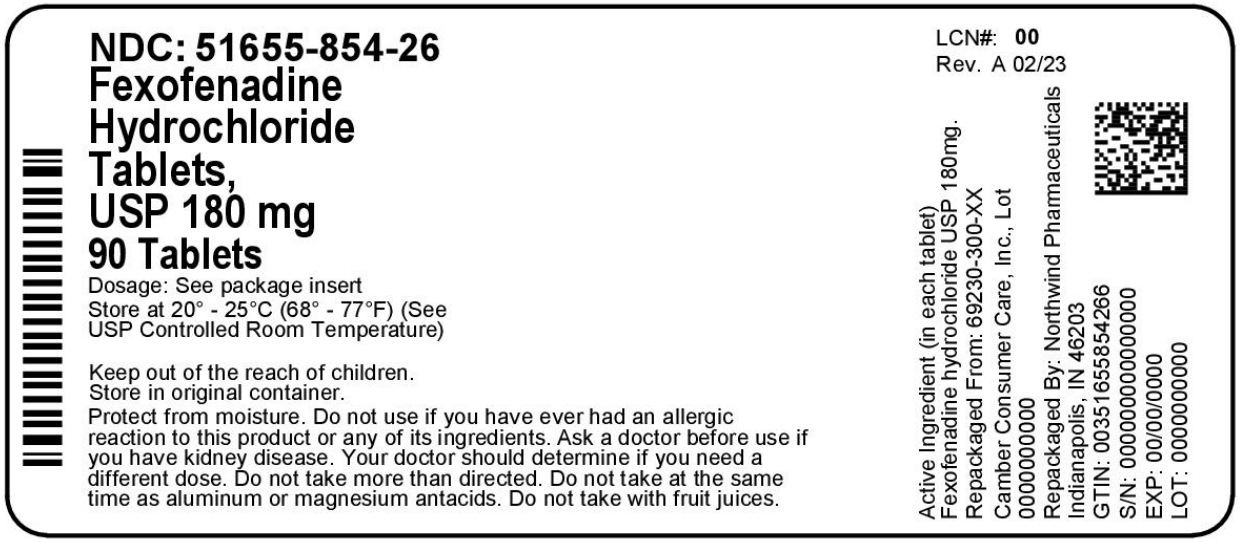
Colloidal silicon dioxide, hypromellose, light liquid paraffin, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, pregelatinized starch, red iron oxide, sodium starch glycolate, talc, titanium dioxide and yellow iron oxide.

**QUESTIONS OR COMMENTS**

call toll-free weekdays 9 AM to 5 PM EST at **1-888-588-1418**

**PRINCIPAL DISPLAY PANEL**

NDC: 51655-854-26




## FEXOFENADINE HCL

fexofenadine hcl tablet

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:51655-854(NDC:69230-300) |
| **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** |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **HYPROMELLOSE 2910 (6 MPA.S)** (UNII: 0WZ8WG20P6) | |
| **LIGHT MINERAL OIL** (UNII: N6K5787QVP) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **POLYSORBATE 80** (UNII: 6OZP39ZG8H) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **FERRIC OXIDE YELLOW** (UNII: EX438O2MRT) | |
| **SODIUM STARCH GLYCOLATE TYPE A POTATO** (UNII: 5856J3G2A2) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **POLYETHYLENE GLYCOL 6000** (UNII: 30IQX730WE) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | pink | **Score** | no score |
| **Shape** | CAPSULE | **Size** | 18mm |

| | | | |
|---|---|---|---|
| **Flavor** | | **Imprint Code** | J;44 |
| **Contains** | | | |

**Packaging**

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:51655-854-26 | 90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 02/07/2023 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA204097 | 02/07/2023 | |

## Labeler - Northwind Pharmaceuticals, LLC (036986393)

## Registrant - Northwind Pharmaceuticals, LLC (036986393)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Northwind Pharmaceuticals, LLC | | 036986393 | repack(51655-854) |

Revised: 3/2023 Northwind Pharmaceuticals, LLC