**FEXOFENADINE HYDROCHLORIDE- fexofenadine hcl tablet**
**Aphena Pharma Solutions - Tennessee, LLC**

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**Major Pharmaceuticals**

**Active ingredient (in each film-coated tablet)**

Fexofenadine HCL 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**

- **each tablet contain**: sodium 8 mg
- store between 20 to 25°C (68 to 77°F)
- protect from excessive moisture
- this product meets the requirements of USP Dissolution Test 2

**Inactive ingredients**

anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, lactose monohydrate, polyethylene glycol, pregelatinized starch (maize), red iron oxide, stearic acid, titanium dioxide, and yellow iron oxide

**Questions or comments?**

Call: **1-800-616-2471**

**Repackaging Information**

Please reference the ***How Supplied*** section listed above for a description of individual tablets. This drug product has been received by Aphena Pharma - TN in a manufacturer or distributor packaged configuration and repackaged in full compliance with all applicable cGMP regulations. The package configurations available from Aphena are listed below:

| Count | 180 mg |
|---|---|
| 30 | 71610-429-30 |

Store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature. Dispense in a tight light-resistant container as defined by USP. Keep this and all drugs out of the reach of children.

Repackaged by:

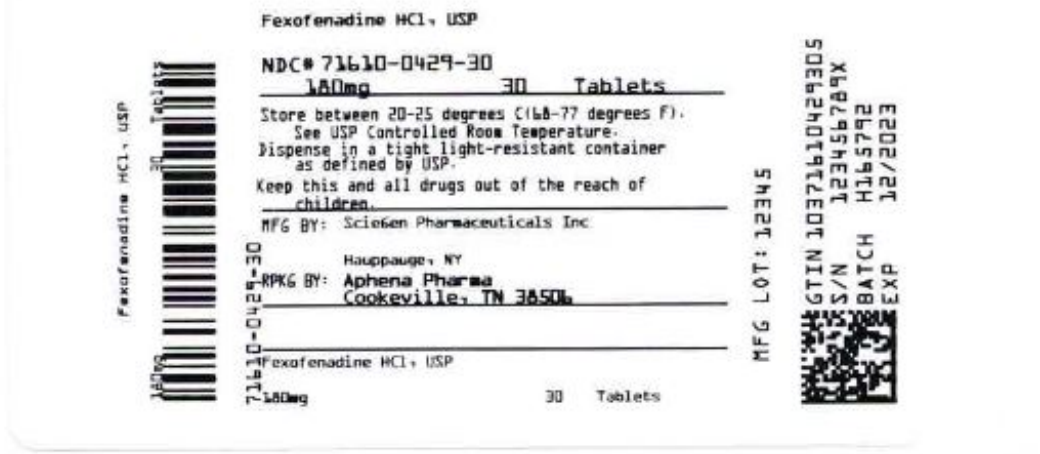
Aphena Pharma Solutions

Cookeville, TN 38506

20200527JH

**PRINCIPAL DISPLAY PANEL - 180 mg**

NDC 71610-429 - Fexofenadine HCl, USP 180 mg Tablets




# FEXOFENADINE HYDROCHLORIDE

fexofenadine hcl tablet

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:71610-429(NDC:0904-7050) |
| **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) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **HYPROMELLOSES** (UNII: 3NXW29V3WO) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **FERRIC OXIDE YELLOW** (UNII: EX438O2MRT) | |
| **ANHYDROUS LACTOSE** (UNII: 3SY5LH9PMK) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WJQ0SDW1A) | |
| **LACTOSE MONOHYDRATE** (UNII: EWQ57Q8I5X) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | WHITE | **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:71610-429-30 | 30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/27/2020 | |
| **2** | NDC:71610-429-60 | 90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/04/2020 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA204507 | 11/29/2019 | |

## Labeler - Aphena Pharma Solutions - Tennessee, LLC (128385585)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Aphena Pharma Solutions - Tennessee, LLC | | 128385585 | REPACK(71610-429) |

Revised: 6/2020 Aphena Pharma Solutions - Tennessee, LLC