

FEXOFENADINE HYDROCHLORIDE- fexofenadine hydrochloride tablet, film coated
Aphena Pharma Solutions - Tennessee, LLC

Perrigo Fexofenadine Hydrochloride Tablets, 180 mg Drug Facts

Active ingredient (in each 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 | take one 180 mg tablet with water once a day; do not take more than |
|-------------------------------------|---|

| | |
|----------------------------------|----------------------|
| and over | 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

- do not use if printed foil under cap is broken or missing
- store at 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

Repackaging Information

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

| Count | 180 mg |
|-------|--------------|
| 30 | 71610-041-30 |
| 90 | 71610-041-60 |

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:



Cookeville, TN 38506

20180222DKJ

PRINCIPAL DISPLAY PANEL - 180mg

NDC 71610-041 Fexofenadine 180mg - Rx Only



FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet, film coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|-------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:716 10-041(NDC:45802-571) |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|----------------------------|----------|
| FEXO FENADINE HYDRO CHLORIDE (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) | |
| FERROSO FERRIC OXIDE (UNII: XM0M87F357) | |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A) | |
| POVIDONES (UNII: FZ989GH94E) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |

Product Characteristics

| | | | |
|-----------------|----------------|---------------------|----------|
| Color | ORANGE (peach) | Score | no score |
| Shape | ROUND | Size | 12mm |
| Flavor | | Imprint Code | 93;7253 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| | | | | |
|---|------------------|---|------------|--|
| 1 | NDC:71610-041-30 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 02/14/2018 | |
| 2 | NDC:71610-041-60 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 02/14/2018 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA076447 | 04/22/2011 | |

Labeler - Aphenia Pharma Solutions - Tennessee, LLC (128385585)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---------|-----------|---------------------|
| Aphenia Pharma Solutions - Tennessee, LLC | | 128385585 | REPACK(71610-041) |

Revised: 2/2018

Aphenia Pharma Solutions - Tennessee, LLC