

FEXOFENADINE HCL- fexofenadine hcl tablet
PD-Rx Pharmaceuticals, Inc.

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

| | |
|--|--|
| 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

- Tamper-Evident: Do not use if seal is missing from bottle.
- 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?

Call **1-800-206-7821**

HOW SUPPLIED

Fexofenadine HCL, 180 mg are pink, capsules debossed with 'J 44' and are supplied as follows:

NDC 72789-196-10 in bottles of 10 tablets

NDC 72789-196-30 in bottles of 30 tablets

NDC 72789-196-90 in bottles of 90 tablets

PRINCIPAL DISPLAY PANEL

Fexofenadine Hydrochloride Tablets USP, 180 mg

| | | | | | | | | | | |
|---|---|--|--|--|--------------------------------|------------|----------------------------------|--------------|-------------------------------|--------------|
| <p>Drug Facts</p> <p>Active Ingredient (in each tablet) Fexofenadine HCl USP 180 mg.....Antihistamine</p> <p>Purpose</p> <p>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</p> <p>Warnings Do not use if you have ever had an allergic reaction to this product or any of its ingredients.</p> <p>Ask a doctor before use if you have kidney disease. Your doctor should determine if you need a different dose.</p> <p>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)</p> <p>Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> | <p>NDC: 72789-196-30</p>  <p>Fexofenadine Hydrochloride 180 mg Antihistamine Non-Drowsy</p> <p>Marketed and Packaged By: PD-Rx Pharmaceuticals, Inc Oklahoma City, OK 73127 1-405-942-3040</p> <p>24 hour</p>  <p>GTIN: 00372789196305 SNO: I22C43000004 EXP: 09/2024 LOT: I22C43</p> <p>30 Tablets TAMPER EVIDENT: DO NOT USE IF SEAL IS BROKEN OR MISSING FROM BOTTLE.</p> | <p>Drug Facts (continued)</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (800) 222-1222 v.8.19.0</p> <p>Directions:</p> <table border="1"> <tr> <td>Adults and children 12 years of age and over</td> <td>take one 180 mg tablet with water once a day; do not take more than 1 tablet in 24 hours</td> </tr> <tr> <td>children under 12 years of age</td> <td>do not use</td> </tr> <tr> <td>adults 65 years of age and older</td> <td>ask a doctor</td> </tr> <tr> <td>consumers with kidney disease</td> <td>ask a doctor</td> </tr> </table> <p>Other information • do not use if foil liner under cap is broken or missing • store at 20° - 25°C (68° - 77°F) • protect from excessive moisture</p> <p>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.</p> <p>Questions? Call 1-800-206-7821</p> | 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 |
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FEXOFENADINE HCL

fexofenadine hcl tablet

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|-------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC: 72789-196(NDC:16714-899) |
| 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 |
|---|----------|
| HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6) | |
| LIGHT MINERAL OIL (UNII: N6K5787QVP) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |

| |
|---|
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) |
| POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE) |
| 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) |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) |

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:72789-196-90 | 90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/06/2021 | |
| 2 | NDC:72789-196-30 | 30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 09/15/2022 | |
| 3 | NDC:72789-196-10 | 10 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/14/2023 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA204097 | 02/18/2019 | |

Labeler - PD-Rx Pharmaceuticals, Inc. (156893695)

Registrant - PD-Rx Pharmaceuticals, Inc. (156893695)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|---------|-----------|---------------------|
| PD-Rx Pharmaceuticals, Inc. | | 156893695 | repack(72789-196) |