

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

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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**

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><b>Drug Facts</b></p> <table border="1"> <tr> <th>Active Ingredient (in each tablet)</th> <th>Purpose</th> </tr> <tr> <td>Fexofenadine HCl USP 180 mg.....</td> <td>Antihistamine</td> </tr> </table> <p><b>Uses</b> 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><b>Warnings</b> <b>Do not use</b> if you have ever had an allergic reaction to this product or any of its ingredients.</p> <p><b>Ask a doctor before use if you have</b> kidney disease. Your doctor should determine if you need a different dose.</p> <p><b>When using this product</b> • 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><b>Stop use and ask a doctor if</b> an allergic reaction to this product occurs. Seek medical help right away.</p> <p><b>If pregnant or breast-feeding</b>, ask a health professional before use.</p>	Active Ingredient (in each tablet)	Purpose	Fexofenadine HCl USP 180 mg.....	Antihistamine	<p>NDC: 72789-196-30</p>  <p><b>Fexofenadine Hydrochloride 180 mg</b> Antihistamine Non-Drowsy <b>24 hour</b></p> <p>Marketed and Packaged By: PD-Rx Pharmaceuticals, Inc Oklahoma City, OK 73127 1-405-942-3040</p>  <p>GTIN: 00372789196305 SNO: I22C43000004 EXP: 09/2024 LOT: I22C43</p> <p><b>30 Tablets</b> TAMPER EVIDENT: DO NOT USE IF SEAL IS BROKEN OR MISSING FROM BOTTLE.</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away (800) 222-1222 v.8.19.0</p> <p><b>Directions:</b></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><b>Other information</b> • 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><b>Inactive Ingredients:</b> 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**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC: 72789-196(NDC:16714-899)
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>FEXOFENADINE HYDROCHLORIDE</b> (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	180 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>HYPROMELLOSE 2910 (6 MPA.S)</b> (UNII: 0WZ8WG20P6)	
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	

<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)
<b>POLYETHYLENE GLYCOL 6000</b> (UNII: 30IQX730WE)
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)
<b>TALC</b> (UNII: 7SEV7J4R1U)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)

### Product Characteristics

<b>Color</b>	pink	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	J;44
<b>Contains</b>			

### 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)