# ALLERGY RELIEF- fexofenadine hcl tablet, coated P & L Development, LLC

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# DRUG FACTS

# Active ingredient (in each tablet)

Fexofenadine HCI USP, 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 (1-800-222-

# Directions

| adults and children 12 years of age and over | take one 180 mg tablet with water once a<br>day;<br>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

- store between 20-25°C (68-77°F)
- protect from excessive moisture

# **Inactive ingredients**

colloidal silicon dioxide, croscarmellose sodium, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, lactose monohydrate, polyethylene glycol, magnesium stearate, microcrystalline cellulose, pregelatinized starch, titanium dioxide

# Questions or comments?

call 1-877-753-3935 Monday-Friday 9AM-5PM EST

# **Principal Display Panel**

Compare to the active ingredient in Allegra® Allergy 24 Hour\*

# allergy relief

fexofenadine HCl tablets USP, 180 mg

antihistamine

for indoor and outdoor allergies

non-drowsy

24 hour relief of

- runny nose
- sneezing,
- itchy, watery eyes
- itchy nose or throat

- for indoor & outdoor allergies
- non-drowsy

caplets\*\*

(\*\*capsule-shaped tablets)

\*This product is not manufactured or distributed by Chattem, Inc., distributor of Allegra® Allergy 24 Hour.

# TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

# KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

# Distributed by: PL Developments

200 Hicks Street, Westbury, NY 11590

# Product Label



**READYinCASE Allergy Relief** 

| ALLERGY RELIEF                  |                |                    |               |  |
|---------------------------------|----------------|--------------------|---------------|--|
| fexofenadine hcl tablet, coated |                |                    |               |  |
|                                 |                |                    |               |  |
| Product Information             |                |                    |               |  |
| Product Type                    | HUMAN OTC DRUG | Item Code (Source) | NDC:59726-801 |  |
| Route of Administration         | ORAL           |                    |               |  |
|                                 |                |                    |               |  |
|                                 |                |                    |               |  |

| Ingredient Name  | Basis of Streng               | gth Strength |
|--|-------------------------------|--------------|
| FEXOFENADINE HYDROCHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V) | FEXOFENADINE<br>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: EX43802MRT)   |                               |              |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)   |                               |              |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)                            |                               |              |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)  |                               |              |
| FERROSOFERRIC OXIDE (UNII: XM0M87F357)   |                               |              |
| STARCH, CORN (UNII: 08232NY3SJ)  |                               |              |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)                                  |                               |              |
| MAGNESIUM STEARATE (UNII: 70097M6I30)  |                               |              |
|  |                               |              |
|  |                               |              |
| Product Characteristics  |                               |              |

| Color    | pink (Peach) | Score        | no score |
|----------|--------------|--------------|----------|
| Shape    | CAPSULE      | Size         | 17mm     |
| Flavor   |              | Imprint Code | G6       |
| Contains |              |              |          |

# Packaging

| # | ltem Code            | Package Description  | Marketing Start<br>Date | Marketing End<br>Date |
|---|----------------------|--|-------------------------|-----------------------|
| 1 | NDC:59726-<br>801-03 | 3 in 1 CARTON  | 08/20/2021              |                       |
| 1 |                      | 1 in 1 BLISTER PACK; Type 0: Not a Combination Product     |                         |                       |
| 2 | NDC:59726-<br>801-12 | 120 in 1 CARTON  | 08/20/2021              |                       |
| 2 |                      | 1 in 1 BLISTER PACK; Type 0: Not a Combination Product     |                         |                       |
| 3 | NDC:59726-<br>801-15 | 15 in 1 CARTON   | 08/20/2021              |                       |
| 3 |                      | 1 in 1 BLISTER PACK; Type 0: Not a Combination Product     |                         |                       |
| 4 | NDC:59726-<br>801-70 | 1 in 1 BOX   | 08/20/2021              |                       |
| 4 |                      | 70 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |                         |                       |
| 5 | NDC:59726-<br>801-30 | 1 in 1 BOX   | 08/20/2021              |                       |
| 5 |                      | 30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |                         |                       |

| Marketing Information |   |                         |                       |  |
|-----------------------|---|-------------------------|-----------------------|--|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |  |
| ANDA                  | ANDA204507                                  | 08/20/2021              |                       |  |
|                       |   |                         |                       |  |

# Labeler - P & L Development, LLC (800014821)

Revised: 3/2023

P & L Development, LLC