#### FEXOFENADINE HCL- fexofenadine hcl tablet NuCare 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 DOCTOR IF

an allergic reaction to this product occurs. Seek medical help right away.

### PREGNANCY/BREASTFEEDING

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

|                                  | take one 180 mg tablet with water once a day; do not take<br>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<br>disease | ask a doctor  |

### Other information

- § Tamper-Evident: Do not use if printed foil seal under cap is missing
- § protect from excessive moisture

### STORAGE

store between 20° and 25°C (68° and 77°F)

#### 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 toll-free weekdays 9 AM to 5 PM EST at 1-888-588-1418

### PRINCIPAL DISPLAY PANEL



| exofenadine hcl tablet   |                      |  |                               |          |  |  |
|--|----------------------|--|-------------------------------|----------|--|--|
| Product Information  |                      |  |                               |          |  |  |
| Product Type   | HUMAN OTC DRUG       | Item Code (Source) NDC:68071-4846(NDC:69230-30 |                               |          |  |  |
| Route of Administration  | ORAL                 |  |                               |          |  |  |
|  |                      |  |                               |          |  |  |
| Active Ingredient/Active   | Moiety               |  |                               |          |  |  |
| Ingre  | edient Name          |  | <b>Basis of Strength</b>      | Strength |  |  |
| EXOFENADINE HYDROCHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE -<br>JNII:E6582LOH6V) |                      |  | FEXOFENADINE<br>HYDROCHLORIDE | 180 mg   |  |  |
|  |                      |  |                               |          |  |  |
| Inactive Ingredients   |                      |  |                               |          |  |  |
| Ingredient Name  |                      |  |                               |          |  |  |
| SILICON DIOXIDE (UNII: ETJ7Z6X   | BU4)                 |  |                               |          |  |  |
| HYPROMELLOSES (UNII: 3NXW29  | V3WO)                |  |                               |          |  |  |
| PARAFFIN (UNII: 1900E3H2ZE)  |                      |  |                               |          |  |  |
| MAGNESIUM STEARATE (UNII: 70   | 097M6I30)            |  |                               |          |  |  |
| CELLULOSE, MICROCRYSTALLII   | NE (UNII: OP1R32D61U | ))   |                               |          |  |  |
| POLYSORBATE 80 (UNII: 60ZP39   | )ZG8H)               |  |                               |          |  |  |
| STARCH, CORN (UNII: 08232NY3   | 5J)                  |  |                               |          |  |  |
| FERRIC OXIDE RED (UNII: 1K09F3   | BG675)               |  |                               |          |  |  |
| FERRIC OXIDE YELLOW (UNII: E)  | (43802MRT)           |  |                               |          |  |  |
| SODIUM STARCH GLYCOLATE T  | YPE A POTATO (UNII   | : 5856J3G2A2)                                  |                               |          |  |  |
| TALC (UNII: 7SEV7J4R1U)  |                      |  |                               |          |  |  |
| TITANIUM DIOXIDE (UNII: 15FIX9)  | V2IP)                |  |                               |          |  |  |

| Product Chara                 | cteristics                         |                           |                         |                       |  |
|-------------------------------|------------------------------------|---------------------------|-------------------------|-----------------------|--|
| Color                         | pink                               | Score                     | Score                   |                       |  |
| Shape                         | CAPSULE                            | Size                      |                         | 18mm                  |  |
| Flavor                        |                                    | Imprint Code              | 2                       | J;44                  |  |
| Contains                      |                                    |                           |                         |                       |  |
|                               |                                    |                           |                         |                       |  |
|                               |                                    |                           |                         |                       |  |
| Packaging                     |                                    |                           |                         |                       |  |
| # Item Code                   | Package D                          | escription                | Marketing Start<br>Date | Marketing End<br>Date |  |
| <b>1</b> NDC:68071-<br>4846-9 | 90 in 1 BOTTLE; Type 0:<br>Product | Not a Combination         | 04/15/2019              |                       |  |
|                               |                                    |                           |                         |                       |  |
|                               |                                    |                           |                         |                       |  |
| Marketing I                   | nformation                         |                           |                         |                       |  |
| Marketing                     |                                    | ber or Monograph<br>ation | Marketing Start<br>Date | Marketing End<br>Date |  |
| Category                      |                                    |                           |                         |                       |  |

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

| Establishment                |         |           |                            |  |  |  |  |
|------------------------------|---------|-----------|----------------------------|--|--|--|--|
| Name                         | Address | ID/FEI    | <b>Business Operations</b> |  |  |  |  |
| NuCare Pharmaceuticals, Inc. |         | 010632300 | repack(68071-4846)         |  |  |  |  |

Revised: 2/2021

NuCare Pharmaceuticals,Inc.