## ALLERGY RELIEF- fexofenadine hydrochloride tablet TOPCO ASSOCIATES LLC

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#### 1192B-TCR-2021-1112

#### 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
- 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 (1-800-222-1222).

## Directions

| 12 years of age and over            | day; do not take more than 1 tablet in 24<br>hours |
|-------------------------------------|--|
| children under 12<br>years of age   | do not use   |
| adults 65 years of<br>age and older | ask a doctor                                       |
| consumers with<br>kidney disease    | ask a doctor                                       |

## Other information

- store between 20-25°C (68-77°F)
- protect from excessive moisture
- retain carton for complete product information and warnings

## Inactive ingredients

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

# PRINCIPAL DISPLAY PANEL

TopCare® health

NDC 36800-653-03

COMPARE TO ALLEGRA® ALLERGY ACTIVE INGREDIENT\*

NON-DROWSY

Allergy Relief

FEXOFENADINE HYDROCHLORIDE TABLETS, 180 mg (ANTIHISTAMINE)

24 HR

INDOOR/OUTDOOR ALLERGY RELIEF

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Nose or Throat

15 TABLETS

actual size



|   | -                    |                   |                           |         |                                      |             |         |                       |  |  |
|---|----------------------|-------------------|---------------------------|---------|--------------------------------------|-------------|---------|-----------------------|--|--|
| A   | LLERGY R             | ELIEF             |                           |         |                                      |             |         |                       |  |  |
| fe>   | ofenadine hy         | drochloride ta    | blet                      |         |                                      |             |         |                       |  |  |
|   |                      |                   |                           |         |                                      |             |         |                       |  |  |
| Ρ   | roduct Info          | rmation           |                           |         |                                      |             |         |                       |  |  |
|   |                      |                   |                           |         |                                      |             |         |                       |  |  |
| Pi  | oduct Type           |                   | HUMAN OTC DRUG            | Item Co | ode (S                               | ource)      | NDC:368 | 00-653                |  |  |
| R   | oute of Admin        | histration        | ORAL                      |         |                                      |             |         |                       |  |  |
|   |                      |                   |                           |         |                                      |             |         |                       |  |  |
|   |                      |                   |                           |         |                                      |             |         |                       |  |  |
| A   | ctive Ingred         | lient/Active      | Moiety                    |         |                                      |             |         |                       |  |  |
|   |                      | Ingre             | dient Name                |         |                                      | Basis of St | rength  | Strength              |  |  |
| FEXOFENADINE HYDROCHLORIDE (UNII: 2S068B75ZU) (FEXOFE<br>UNII:E6582LOH6V) |                      |                   | OFENADIN                  | IE -    | FEXOFENADINE<br>HYDROCHLORIDE 180 mg |             |         |                       |  |  |
|   |                      |                   |                           |         |                                      |             |         |                       |  |  |
|   |                      |                   |                           |         |                                      |             |         |                       |  |  |
| In  | active Ingr          | edients           |                           |         |                                      |             |         |                       |  |  |
|   |                      |                   | Ingredient Name           |         |                                      |             | St      | rength                |  |  |
| CF  | OSCARMELLOS          | SE SODIUM (UN     | II: M28OL1HH48)           |         |                                      |             |         |                       |  |  |
| FE  | RROSOFERRIC          | OXIDE (UNII: XM   | 10M87F357)                |         |                                      |             |         |                       |  |  |
| FE  | RRIC OXIDE RE        | D (UNII: 1K09F30  | G675)                     |         |                                      |             |         |                       |  |  |
| FE  | RRIC OXIDE YE        | LLOW (UNII: EX    | 43802MRT)                 |         |                                      |             |         |                       |  |  |
| HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)                           |                      |                   |                           |         |                                      |             |         |                       |  |  |
| LA  | CTOSE MONOR          | HYDRATE (UNII:    | EWQ57Q8I5X)               |         |                                      |             |         |                       |  |  |
| MAGNESIUM STEARATE (UNII: 70097M6I30)                                     |                      |                   |                           |         |                                      |             |         |                       |  |  |
| М   | CROCRYSTALL          | INE CELLULOSE     | (UNII: OP1R32D61U)        |         |                                      |             |         |                       |  |  |
|   |                      |                   | JNII: 30IQX730WE)         |         |                                      |             |         |                       |  |  |
|   |                      | (UNII: ETJ7Z6XB   |                           |         |                                      |             |         |                       |  |  |
|   |                      | JNII: 08232NY35   |                           |         |                                      |             |         |                       |  |  |
| Τľ  |                      | DE (UNII: 15FIX9V | 2JP)                      |         |                                      |             |         |                       |  |  |
|   |                      |                   |                           |         |                                      |             |         |                       |  |  |
| -   |                      |                   |                           |         |                                      |             |         |                       |  |  |
|   | roduct Char          |                   |                           |         |                                      |             |         |                       |  |  |
|   | olor                 | orange ((PE       |                           |         | ore                                  |             | no so   |                       |  |  |
| Shape   |                      | OVAL (Caps)       | ule-shaped)               |         | Size                                 |             | 17mm    |                       |  |  |
| Flavor  |                      |                   |                           | Im      | mprint Code                          |             | G6      |                       |  |  |
| Сс  | ontains              |                   |                           |         |                                      |             |         |                       |  |  |
|   |                      |                   |                           |         |                                      |             |         |                       |  |  |
| Pa  | ackaging             |                   |                           |         |                                      |             |         |                       |  |  |
| #   | ltem Code            | Pa                | ckage Description         |         | Marketing Start I<br>Date            |             |         | Marketing End<br>Date |  |  |
| 1   | NDC:36800-<br>653-03 | 1 in 1 CARTON     |                           |         | 09/10                                |             |         |                       |  |  |
| -   |                      | 15 in 1 BLISTER   | PACK; Type 0: Not a Combi | ination |                                      |             |         |                       |  |  |
| 1   |                      | Product           |                           |         |                                      |             |         |                       |  |  |
|   |                      |                   |                           |         |                                      |             |         |                       |  |  |

08/31/2021

08/31/2021

06/30/2025

06/30/2025

NDC:36800-

653-16

**3** NDC:36800-653-14 2 in 1 CARTON

**Combination Product** 

**Combination Product** 

30 in 1 BOTTLE, PLASTIC; Type 0: Not a

180 in 1 BOTTLE, PLASTIC; Type 0: Not a

2

2

| 4                     |                      |   |                         |                       |  |
|-----------------------|----------------------|---|-------------------------|-----------------------|--|
| +                     | NDC:36800-<br>653-06 | 1 in 1 CARTON   | 11/16/2021              | 11/30/2023            |  |
| 4                     |                      | 45 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  |                         |                       |  |
| 5                     | NDC:36800-<br>653-07 | 1 in 1 CARTON   | 12/08/2022              |                       |  |
| 5                     |                      | 60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  |                         |                       |  |
| 6                     | NDC:36800-<br>653-11 | 1 in 1 CARTON 12/08/2023                                    |                         |                       |  |
| 6                     |                      | 150 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |                         |                       |  |
| M                     | larketing            | Information   |                         |                       |  |
| Marketing<br>Category |                      | Application Number or Monograph<br>Citation                 | Marketing Start<br>Date | Marketing End<br>Date |  |
|                       |                      | ANDA211075  | 08/31/2021              |                       |  |

Labeler - TOPCO ASSOCIATES LLC (006935977)

Revised: 10/2023

TOPCO ASSOCIATES LLC