# CHILDRENS ALLEGRA ALLERGY- fexofenadine hydrochloride suspension Chattem, Inc.

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#### **Childrens Allegra Allergy Oral Suspension**

#### **Drug Facts**

#### Active ingredient

#### (in each 5 mL)

Fexofenadine HCI 30 mg

#### Purpose

Antihistamine

#### Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, water 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

- shake well before using
- use only with enclosed dosing cup

| adults and children 12 years of age and over | take 10 mL every 12 hours; do not take more than 20 mL in 24 hours |
|--|--|
| children 2 to under 12 years of age          | take 5 mL every 12 hours; do not take more than 10 mL in 24 hours  |
| children under 2 years of age                | ask a doctor   |
| adults 65 years of age and older             | ask a doctor   |
| consumers with kidney disease                | ask a doctor   |

Note: mL = milliliters

#### Other information

- each 5 mL contains: each 5 mL contains: potassium 5 mg and sodium 19 mg
- safety sealed: do not use if carton is opened or if printed foil inner seal on bottle is torn or missing
- store between 20° and 25°C (68° and 77°F)
- color change from white to beige is expected over time. This does not impact product effectiveness and safety.

#### Inactive ingredients

edetate disodium, flavor, poloxamer 407, potassium sorbate, propylene glycol, purified water, sodium phosphate dibasic heptahydrate, sodium phosphate monobasic monohydrate, sucrose, titanium dioxide, xanthan gum, xylitol

#### **Questions or comments?**

call toll-free **1-800-844-2798** 

#### PRINCIPAL DISPLAY PANEL

NDC 41167-4244-4 Children's Allegra® ALLERGY fexofenadine HCI oral suspension 12 HR



#### PRINCIPAL DISPLAY PANEL

NDC 41167-4246-4 Children's Allegra® ALLERGY fexofenadine HCI oral suspension 12 HR 30 mg/5 ml antihistamine



| CHILDRENS ALLEGRA ALLERGY<br>fexofenadine hydrochloride suspension |                |               |        |          |        |  |  |
|--|----------------|---------------|--------|----------|--------|--|--|
|  |                |               |        |          |        |  |  |
| Product Information  |                |               |        |          |        |  |  |
| Product Type   | HUMAN OTC DRUG | Item Code (Se | ource) | NDC:4116 | 7-4244 |  |  |
| Route of Administration  | ORAL           |               |        |          |        |  |  |
|  |                |               |        |          |        |  |  |
|  |                |               |        |          |        |  |  |
| Active Ingredient/Active Moiety                                    |                |               |        |          |        |  |  |
| Ingredient Name Basis of Strength Strength                         |                |               |        |          |        |  |  |

|   | edients   |  |   |                                  |                       |  |
|---|---|--|---|----------------------------------|-----------------------|--|
| Ingredient Name<br>EDETATE DISODIUM (UNII: 7FLD91C86K)  |   |  |   |                                  | Strength              |  |
|   |   |  |   |                                  |                       |  |
| POLOXAMER 407 (UNII: TUF2IVW3M2)  |   |  |   |                                  |                       |  |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)   |   |  |   |                                  |                       |  |
|   |   |  |   |                                  |                       |  |
| SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE (UNII: 70WT22SF4B)  |   |  |   |                                  |                       |  |
| SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)<br>SUCROSE (UNII: C151H8M554)   |   |  |   |                                  |                       |  |
|   |   | סוכ  |   |                                  |                       |  |
| XANTHAN GUM (L  |   | -  |   |                                  |                       |  |
| POTASSIUM SOR   |   |  |   |                                  |                       |  |
| XYLITOL (UNII: VC   |   | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,                            |   |                                  |                       |  |
|   | <b>40004</b> ,  |  |   |                                  |                       |  |
|   |   |  |   |                                  |                       |  |
| Product Char  | acteristics   |  |   |                                  |                       |  |
| Color   |   | white  | Score   |                                  |                       |  |
| Shape   |   |  | Size  |                                  |                       |  |
| Flavor  |   | BERRY  | Imprint Co  | Imprint Code                     |                       |  |
| Contoire  |   |  |   |                                  |                       |  |
|   |   |  |   |                                  |                       |  |
| Contains Packaging # Item Code  | Pa  | ckage Descrip  | otion   | Marketing Start<br>Date          |                       |  |
| Packaging<br># Item Code  |   | ckage Descrip  | otion   | Date                             | Marketing End<br>Date |  |
| Packaging<br># Item Code  | 1 in 1 CARTON   | -  |   |                                  |                       |  |
| Packaging<br># Item Code  | 1 in 1 CARTON   | <b>ckage Descrip</b><br>DTTLE; Type 0: No                          |   | Date                             |                       |  |
| Packaging           #         Item Code           1         NDC:41167-<br>4244-4  | 1 in 1 CARTON<br>120 mL in 1 BC   | -  |   | Date                             |                       |  |
| Packaging         #       Item Code         1       NDC:41167-<br>4244-4         1       NDC:41167-<br>2000         2       NDC:41167-  | 1 in 1 CARTON<br>120 mL in 1 BC<br>Product<br>1 in 1 CARTON   | -  | t a Combination                                       | <b>Date</b><br>03/03/2011        |                       |  |
| Packaging         #       Item Code         1       NDC:41167-<br>4244-4         1       NDC:41167-<br>4244-1         2       NDC:41167-<br>4244-1  | 1 in 1 CARTON<br>120 mL in 1 BC<br>Product<br>1 in 1 CARTON<br>240 mL in 1 BC   | OTTLE; Type 0: No<br>OTTLE; Type 0: No                             | t a Combination                                       | <b>Date</b><br>03/03/2011        |                       |  |
| Packaging         item Code         1       NDC:41167-<br>4244-4         2       NDC:41167-<br>4244-1         2       NDC:41167-<br>4244-1         2       NDC:41167-<br>4244-1   | 1 in 1 CARTON<br>120 mL in 1 BC<br>Product<br>1 in 1 CARTON<br>240 mL in 1 BC<br>Product<br>3 in 1 CELLO PA   | OTTLE; Type 0: No<br>OTTLE; Type 0: No                             | t a Combination<br>t a Combination                    | Date<br>03/03/2011<br>03/03/2011 |                       |  |
| P       kaging         Item Code         I       NDC:41167-         I       NDC:41167- | 1 in 1 CARTON<br>120 mL in 1 BC<br>Product<br>1 in 1 CARTON<br>240 mL in 1 BC<br>Product<br>3 in 1 CELLO PA<br>120 mL in 1 BC   | OTTLE; Type 0: No<br>OTTLE; Type 0: No<br>ACK                      | t a Combination<br>t a Combination                    | Date<br>03/03/2011<br>03/03/2011 |                       |  |
| P       kaging         Item Code         I       NDC:41167-         I       NDC:41167- | <ul> <li>1 in 1 CARTON</li> <li>120 mL in 1 BC<br/>Product</li> <li>1 in 1 CARTON</li> <li>240 mL in 1 BC<br/>Product</li> <li>3 in 1 CELLO PA</li> <li>120 mL in 1 BC<br/>Product</li> </ul> | OTTLE; Type 0: No<br>OTTLE; Type 0: No<br>ACK<br>OTTLE; Type 0: No | t a Combination<br>t a Combination                    | Date<br>03/03/2011<br>03/03/2011 |                       |  |
| P   | 1 in 1 CARTON<br>120 mL in 1 BC<br>Product<br>1 in 1 CARTON<br>240 mL in 1 BC<br>Product<br>3 in 1 CELLO PA<br>120 mL in 1 BC<br>Product<br>HIGORMAN  | OTTLE; Type 0: No<br>OTTLE; Type 0: No<br>ACK<br>OTTLE; Type 0: No | t a Combination<br>t a Combination<br>t a Combination | Date<br>03/03/2011<br>03/03/2011 | Marketing Enc<br>Date |  |

### **CHILDRENS ALLEGRA ALLERGY**

| P   | roduct Info            | rmation   |                      |                   |                              |          |                 |     |
|---|------------------------|---|----------------------|-------------------|------------------------------|----------|-----------------|-----|
| Pı  | oduct Type             |   | HUMAN OTC DRUG       | Item Code         | (Source)                     | NDC:4116 | 2:41167-4246    |     |
| Ro  | oute of Admin          | istration   | ORAL                 |                   |                              |          |                 |     |
| A   | ctive Ingred           | ient/Active   | Moiety               |                   |                              |          |                 |     |
|   |                        | Ingree  | dient Name           |                   | Basis of St                  | rength   | Strer           | ngt |
| FEXOFENADINE HYDROCHLORIDE (UNII: 250<br>UNII:E6582LOH6V) |                        |   | DE (UNII: 2S068B75ZU | ) (FEXOFENADINE - | FEXOFENADINE<br>HYDROCHLORID | E        | 30 mg<br>in 5 m |     |
| In  | active Ingre           | edients   |                      |                   |                              |          |                 |     |
|   |                        |   | Ingredient N         | ame               |                              |          | Streng          | gth |
|   |                        |   |                      |                   |                              |          |                 |     |
|   | LOXAMER 407            |   |                      |                   |                              |          |                 |     |
|   |                        |   | Q167V3)              |                   |                              |          |                 |     |
|   | ATER (UNII: 0590       |   | HEPTAHYDRATE (UN     |                   |                              |          |                 |     |
|   |                        |   | SIC, MONOHYDRATE     |                   | RNI)                         |          |                 |     |
|   | CROSE (UNII: C         |   |                      |                   | (1)                          |          |                 |     |
|   |                        |   | 2IP)                 |                   |                              |          |                 |     |
|   | NTHAN GUM (U           |   | -                    |                   |                              |          |                 |     |
|   | TASSIUM SORI           |   |                      |                   |                              |          |                 |     |
| XY  | <b>LITOL</b> (UNII: VC | Q006KQ1E)   |                      |                   |                              |          |                 |     |
|   |                        |   |                      |                   |                              |          |                 |     |
| D   | roduct Char            | actoristics   |                      |                   |                              |          |                 |     |
|   |                        | acteristics   | white                | <b>C</b>          |                              |          |                 |     |
|   | olor                   |   | white                | Score             |                              |          |                 |     |
|   | ape                    |   | GRAPE                | Size              |                              |          |                 |     |
|   | avor<br>Intains        |   | GRAPE                | Imprint Code      |                              |          |                 |     |
|   | ontains                |   |                      |                   |                              |          |                 |     |
|   |                        |   |                      |                   |                              |          |                 |     |
| Pa  | ackaging               |   |                      |                   |                              |          |                 |     |
| #   | ltem Code              | Pa  | ckage Descriptio     | n M               | arketing Start<br>Date       |          | eting E<br>Date | End |
| 1   | NDC:41167-<br>4246-4   | 1 in 1 CARTON   |                      | 03/0              | 01/2023                      |          |                 |     |
| 1   |                        | 120 mL in 1 BOTTLE; Type 0: Not a Combinat<br>Product |                      | Combination       |                              |          |                 |     |
| 2   | NDC:41167-<br>4246-2   | 1 in 1 CARTON   |                      | 03/0              | 01/2023                      |          |                 |     |
|   |                        | 240 mL in 1 BOTTLE; Type 0: Not a Combination Product |                      |                   |                              |          |                 |     |
| 2   |                        | Product   |                      |                   |                              |          |                 |     |

| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
|-----------------------|---|-------------------------|-----------------------|
| NDA                   | NDA201373                                   | 03/03/2011              |                       |
|                       |   |                         |                       |

## Labeler - Chattem, Inc. (003336013)

Revised: 2/2024

Chattem, Inc.