ALLERGY RELIEF- fexofenadine hydrochloride tablet P and L Development of New York Corporation

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
- 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 right away.

Directions

| adults and children 12 years of | take one 180 mg tablet with water once a day; do not take more than |
|---------------------------------|---------------------------------------------------------------------|
| age and over | 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 at 20°-25°C (68°-77°F)
- protect from excessive moisture

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, hypromellose, iron oxide red, iron oxide yellow, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone k-30, talc, titanium dioxide.

Questions or comments?

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

Package/Label Principal Display Panel

†Compare to the active ingredient in Allegra® Allergy 24 hour

ORIGINAL PRESCRIPTION STRENGTH

NON-DROWSY

ALLERGY RELIEF

Fexofenadine HCl 180 mg

Antihistamine

ALLERGY

Indoor and outdoor Allergies

24 Hour Relief of:

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

†This product is not manufactured or distributed by Chattem Inc., distributor of Allegra® Allergy 24 hour

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION. DO NOT USE IF CARTON IS OPEN OR IF INDIVIDUAL BLISTER UNIT IS TORN OR OPEN.

Distributed by: PL Developments

200 hicks street

westbury NY 11590

PRODUCT OF INDIA

Product Label

Questions or comments? Call toll free 1-877-753-3935 Monday-Friday 9AM-5PM EST

Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, hypromellose, iron oxide red, iron oxide yellow, actose monohydrale, magnesium stearale, microcrystaliline cellulose, polyethylene glycol, povidone K-30, talc, titanium dioxide actose monohydrale, magnesium stearale, microcrystaliline cellulose, polyethylene glycol, povidone K-30, talc, titanium dioxide

| ■ protect from excessive moisture | 5°C (68° to 77°F) | S ot °OS is enois ■ | Other information |
|-----------------------------------|-------------------|---------------------|------------------------------|
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do not take with fruit juices (see Directions) Ask a doctor before use if you have kidney disease. Your doctor should determine if you need a different dose. Do not use it you have ever had an allergic reaction to this product or any of its ingredients. Warnings

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

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Inchry, watery eyes

Inchry, watery eyes

Inchry, watery eyes

Fexofenadine HCI 180 mg. 9UIMB3SIUI3UA Purpose

Active ingredient (in each tablet) Drug Facts

Allergy Relief

5 TABLETS 180 mg each

†Compare to the active ingredient in Allegra® Allergy 24 Hour

ORIGINAL PRESCRIPTION STRENGTH

Allergy Relief

NDC 59726-189-05

Fexofenadine HCI 180 mg

Antihistamine Allergy

Indoor and Outdoor Allergies

5 TABLETS 180 mg each

Fexofenadine HCI 180 mg **Antihistamine** Allergy

Indoor and Outdoor Allergies

5 TABLETS

180 mg each

24 Hour Relief of:

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

Date: Lot No.:

DO NOT USE IF CARTON IS OPEN OR IF INDIVIDUAL BLISTER UNIT IS TORN OR OPEN. KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

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Distributed by: PL Developments Westbury, NY 11590, USA

PLD-A FC000476



Fexofenadine HCl 180 mg

fexofenadine hcl tablet

| Product Information | | | |
|-------------------------|-------------------------|--------------------|-----------------------------------|
| Product Type | HUMAN OTC DRUG LABEL | Item Code (Source) | NDC:59726- 189 (NDC:55648-987) |
| Route of Administration | ORAL | DEA Schedule | |

| Active Ingredient/Active Moiety | | |
|-----------------------------------------------|----------------------------|----------|
| Ingredient Name | Basis of Strength | Strength |
| FEXO FENADINE HYDRO CHLO RIDE (FEXO FENADINE) | FEXOFENADINE HYDROCHLORIDE | 180 mg |

| Inactive Ingredients | | | | |
|-------------------------------|----------|--|--|--|
| Ingredient Name | Strength | | | |
| SILICON DIO XIDE | | | | |
| CROSCARMELLOSE SODIUM | | | | |
| HYPROMELLOSES | | | | |
| FERRIC O XIDE RED | | | | |
| FERRIC OXIDE YELLOW | | | | |
| LACTO SE MONO HYDRATE | | | | |
| MAGNESIUM STEARATE | | | | |
| CELLULO SE, MICRO CRYSTALLINE | | | | |
| POLYETHYLENE GLYCOLS | | | | |
| PO VIDONE K30 | | | | |
| TALC | | | | |
| TITANIUM DIO XIDE | | | | |

| Product Characteristics | | | | |
|-------------------------|---------------------|--------------|----------|--|
| Color | WHITE (light peach) | Score | no score | |
| Shape | CAPSULE | Size | 17mm | |
| Flavor | | Imprint Code | W987 | |
| Contains | | | | |

| F | Packaging | | | | |
|---|------------------|---------------------|----------------------|--------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:59726-189-05 | 1 in 1 CARTON | | | |
| 1 | | 5 in 1 BLISTER PACK | | | |

| Marketing Information | | | | |
|-----------------------|------------------------------------------|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| ANDA | ANDA079112 | 03/28/2013 | | |
| | | | | |

Labeler - P and L Development of New York Corporation (800014821)

Registrant - P and L Development of New York Corporation (800014821)

Revised: 12/2012 P and L Development of New York Corporation