

FEXOFENADINE HCL- fexofenadine hcl tablet
QUALITY CHOICE (Chain Drug Marketing Association)

DRUG FACTS

Active ingredient (in each film-coated tablet)

Fexofenadine HCl 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 right away.

Directions

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

- each tablet contains: sodium 8 mg
- store between 20-25°C (68-77°F)
- protect from excessive moisture
- this product meets the requirements of USP Dissolution Test 2

Inactive ingredients

anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, lactose monohydrate, pregelatinized starch (maize), stearic acid, opadry pink 03B84893 containing hypromellose, polyethylene glycol, red iron oxide, titanium dioxide, and yellow iron oxide

Questions or comments?

call **1-248-449-9300 Monday- Friday 9AM- 5PM EST**

Principal Display Panel

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

ORIGINAL PRESCRIPTION STRENGTH

Fexofenadine hydrochloride

tablets USP, 180 mg / Antihistamine

Indoor and outdoor allergies

Non-Drowsy

24 Hour Relief of:

sneezing

runny nose

itchy, watery eyes

itchy nose or throat

Tablets

†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.

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

Distributed by C.D.M.A., Inc. ©

43157 W. Nine Mile

Novi, MI 48376-0995

www.qualitychoice.com

Product Label

| | | | | | |
|---|---------------------------------|--|--|-------------------------------|--------------|
| Drug Facts | | Drug Facts (continued) | | | |
| Active ingredient (in each film-coated tablet) Fexofenadine HCl USP 180 mg | Purpose Antihistamine | Directions adults and children 12 years of age and over | take one 180 mg tablet with water once a day; do not take more than 1 tablet in 24 hours | | |
| 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 | | children under 12 years of age | do not use | | |
| 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. | | adults 65 years of age and older | ask a doctor | | |
| | | Other information ■ each tablet contains: sodium 8 mg ■ store between 20°-25°C (68°-77°F) ■ protect from excessive moisture ■ this product meets the requirements of USP Dissolution Test 2 | | consumers with kidney disease | ask a doctor |
| | | Inactive ingredients anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, lactose monohydrate, pregelatinized starch (maize), stearic acid, opadry pink 03384893 containing hypromellose, polyethylene glycol, red iron oxide, titanium dioxide, and yellow iron oxide | | | |
| | | Questions or comments? Call 1-248-449-9300 Monday-Friday 9AM-5PM EST | | | |

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.



NDC 63868-141-30

Original prescription strength

Fexofenadine Hydrochloride Tablets USP, 180 mg Antihistamine

For Indoor & Outdoor Allergies

30 Tablets (180 mg each)

Original prescription strength

Fexofenadine Hydrochloride Tablets USP, 180 mg/Antihistamine

For Indoor & Outdoor Allergies

Non-Drowsy

24 Hour Relief of:

Sneezing
Runny Nose
Itchy, Watery Eyes
Itchy Nose or Throat



30 Tablets (180 mg each)

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



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 43157 W. Nine Mile
 Novi, MI 48376-0995
 www.qualitychoice.com
 Questions: 248-449-9300

PLD-4416A
F0203544

1 BOTTLE INSIDE

Lot No:
Exp. Date:

Quality Choice Fexofenadine Hydrochloride Tablets USP, 180 mg

FEXOFENADINE HCL

fexofenadine hcl tablet

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63868-141 |
| Route of Administration | ORAL | | |

| Active Ingredient/Active Moiety | | | | |
|--|--|--|----------------------|--------------------|
| Ingredient Name | | Basis of Strength | Strength | |
| FEXOFENADINE HYDROCHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V) | | FEXOFENADINE HYDROCHLORIDE | 180 mg | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | | | | |
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | | | | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | | | | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | | | | |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | | | | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | | | | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | | | | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | | | | |
| ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK) | | | | |
| STARCH, CORN (UNII: O8232NY3SJ) | | | | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | | | | |
| Product Characteristics | | | | |
| Color | white | Score | no score | |
| Shape | CAPSULE | Size | 17mm | |
| Flavor | | Imprint Code | SG;202 | |
| Contains | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:63868-141-30 | 1 in 1 BOX | 03/31/2016 | 03/31/2025 |
| 1 | | 30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| ANDA | ANDA079112 | 03/31/2016 | 03/31/2025 | |

Labeler - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)