

**PICNIC ANTIHISTAMINE- fexofenadine hcl tablet, film coated
30M One, Inc.**

Thirty Madison Inc Antihistamine 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 (1-800-222-1222).

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

- do not use if carton is opened or printed foil under cap is broken or missing
- store between 20°-25°C (68°-77°F)
- protect from excessive moisture
- this product meets the requirements of USP *Dissolution Test 3*

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, titanium dioxide

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

ALLERGY

FEXOFENADINE HYDROCHLORIDE TABLETS 180 mg

Antihistamine

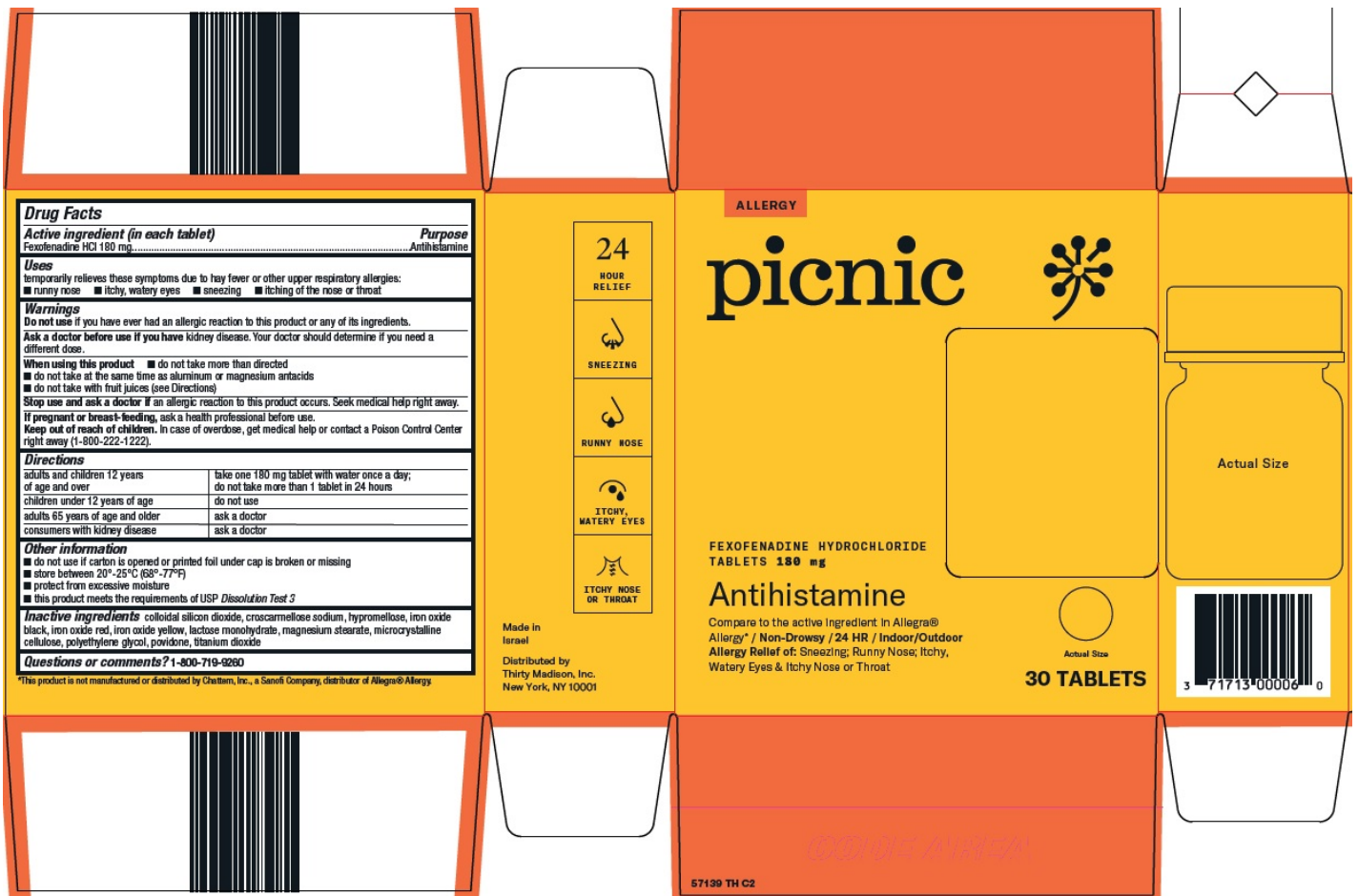
Compare to the active ingredient in Allegra®

Allergy / Non-Drowsy / 24 HR / Indoor/Outdoor

Allergy Relief of: Sneezing; Runny Nose; Itchy, Watery Eyes & Itchy Nose or Throat

Actual Size

30 TABLETS



PICNIC ANTIHISTAMINE

fexofenadine hcl tablet, film coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:80159-102 |
| 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) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| FERROSFERRIC OXIDE (UNII: XMOM87F357) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| FERRIC OXIDE YELLOW (UNII: EX43802MRT) | |

| | |
|--|--|
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|-----------------|----------------|---------------------|----------|
| Color | ORANGE (peach) | Score | no score |
| Shape | ROUND | Size | 12mm |
| Flavor | | Imprint Code | 93;7253 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:80159-102-01 | 1 in 1 CARTON | 01/19/2021 | |
| 1 | | 30 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:80159-102-03 | 1 in 1 CARTON | 01/19/2021 | |
| 2 | | 90 in 1 BOTTLE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA076447 | 01/19/2021 | |

Labeler - 30M One, Inc. (117621005)

Revised: 5/2021

30M One, Inc.