GUAIFENESIN- guaifenesin tablet, extended release KROGER COMPANY

GUAIFENESIN EXTENDED-RELEASE TABLETS, 1200 mg 14ct and 28ct

Drug Facts

Active ingredient (in each extended-release tablet)

Guaifenesin 1200 mg

Purpose

Expectorant

Uses

helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

Warnings

Do not use

• for children under 12 years of age

Ask a doctor before use if you have

- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough accompanied by too much phlegm (mucus)

Stop use and ask a doctor if

• cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious illness.

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

- do not crush, chew, or break tablet
- take with a full glass of water
- this product can be administered without regard for the timing of meals
- adults and children 12 years of age and over: 1 tablet every 12 hours. Do not exceed 2 tablets in 24 hours.
- children under 12 years of age: do not use

Other information

- Tamper evident: Do not use if carton is open or if printed seal on blister is broken or missing.
- store between 20-25°C (68-77°F)

Inactive ingredients

carbomer homopolymer type B; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF

Questions or comments?

1-800-632-6900

You may also report side effects to this phone number.

DISTRIBUTED BY THE KROGER CO. CINCINNATI, OHIO 45202

PRINCIPAL DISPLAY PANEL - 1200 mg Tablet Blister Pack Carton

COMPARE TO the active ingredient of MAXIMUM STRENGTH MUCINEX[®]* See back panel

NDC 30142-703-14

 $Kroger_{\mathbb{R}}$

OUR PHARMACIST RECOMMENDED

Maximum Strength

Mucus Relief ER-Max

Guaifenesin 1200 mg, Extended-Release Tablets

EXPECTORANT

12

HOUR

- Relieves Chest Congestion
- Thins & Loosens Mucus
- Immediate & Extended Release

actual

size

14 EXTENDED-RELEASE TABLETS







| GUAIFENESIN | | | | | | | | | |
|--|-----------------|--|-------------------|-------|----------|-------------------|-----------------------|-------------|--|
| guaifenesin tablet, extended release | | | | | | | | | |
| | | | | | | | | | |
| Product Information | on | | | | | | | | |
| Product Type | | HUMAN OTC DRUG Item Code (So | | | de (Sou | ırce) | NDC: 30142-703 | | |
| Route of Administration | on | ORAL | | | | | | | |
| | | | | | | | | | |
| Active Ingredient/Active Moiety | | | | | | | | | |
| Ingredient Name | | | | | | Basis of Strength | | Strength | |
| Guaifenesin (UNII: 495W | 7451VQ) (Gua | ifenesin - V | UNII:495W7451VQ) | | | Guaifenesin 1 | | 1200 mg | |
| | | | | | | | | | |
| Inactive Ingredients | | | | | | | | | |
| macuve mgreulen | 15 | | Ingredient Name | | | | | Strength | |
| CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31) | | | | | | Strength | | | |
| hypromellose, unspecified (UNII: 3NXW29V3WO) | | | | | | | | | |
| magnesium stearate (UNII: 70097M6I30) | | | | | | | | | |
| microcrystalline cellulose (UNII: OP1R32D61U) | | | | | | | | | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | | | | | | | | | |
| | | | | | | | | | |
| Product Characteristics | | | | | | | | | |
| Color | IS UCS WHITE | | E como | | | DO 660 P | | | |
| Shape | OVAL | | Score Size | | | 22mm | | | |
| Flavor | OVIL | | | | | Mxeunic;1200 | | | |
| Contains | | | Imprint Code | | | All culle, 1200 | | | |
| Contains | | | | | | | | | |
| | | | | | | | | | |
| Packaging | | | | | | | | | |
| # Item Code | | Package | Description | | Marke | ting Start Date | Marketii | ng End Date | |
| 1 NDC:30142-703-14 14 | in 1 BLISTER | BLISTER PACK; Type 0: Not a Combination Pr | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| Marketing Information | | | | | | | | | |
| Marketing Category | | on Numbe | r or Monograph Ci | ation | Marke | ting Start Date | Marketir | ng End Date | |
| NDA | NDA021282 | | | | 08/21/20 | 0 | | - | |
| | | | | | | | | | |

Labeler - KROGER COMPANY (006999528)

Establishment

| Name | Address | | Business Operations |
|--|---------|-----------|--|
| RECKITT BENCKISER HEALTHCARE INTERNATIONAL LTD | | 230780363 | MANUFACTURE(30142-703), LABEL(30142- 703) |

Revised: 2/2020

KROGER COMPANY