GUAIFENESIN- guaifenesin tablet, extended release CVS PHARMACY, INC

GUAIFENESIN EXTENDED-RELEASE TABLETS, 600 mg

Drug Facts

Active ingredient (in each extended-release tablet)

Guaifenesin 600 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

- persistant 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 or 2 tablets every 12 hours. Do not exceed 4 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?

(1-800-406-7984)

You may also report side effects to this phone number.

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

PRINCIPAL DISPLAY PANEL - 600 mg Tablet Blister Pack Carton

CVS

Health_®

Compare to the active ingredient in Mucinex[®]*

NDC 51316-070-68

Mucus

Extended

Release

12

HOUR

GUAIFENESIN EXTENDED-RELEASE TABLETS, 600 mg

EXPECTORANT

- Relieves chest congestion
- Thins & loosens mucus
- Immediate & extended release

Actual Size

68 EXTENDED-

RELEASE TABLETS



Mucus Extended Release

GUAIFENESIN EXTENDED-RELEASE TABLETS, 600 mg

EXPECTORANT

♥CVS Health.

- · Relieves chest congestion
- Thins & loosens mucus
- Immediate & extended release



Mucus Extended Release



GUAIFENESIN EXTENDED-RELEASE TABLETS, 600 mg

EXPECTORANT

- · Relieves chest congestion
- Thins & loosens mucus
- Immediate & extended release



68 EXTENDED-RELEASE TABLETS

Mucus Extended Release

GUAIFENESIN EXTENDED-RELEASE TABLETS, 600 mg

EXPECTORANT

CVS

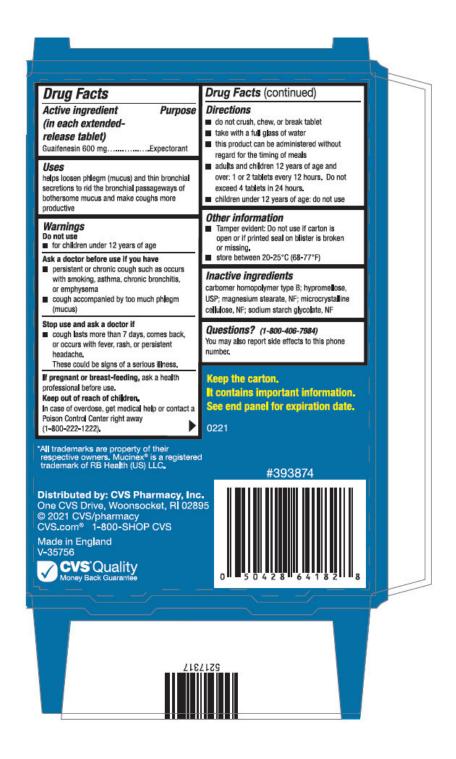
Health.

- Relieves chest congestion
- Thins & loosens mucus
- Immediate & extended release









GUAIFENESIN

guaifenesin tablet, extended release

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:51316-070 Route of Administration ORAL

| Active Ingredient/Active Moiety | | | | |
|---------------------------------|----------|--|--|--|
| Basis of Strength | Strength | | | |
| Guaifenesin | 600 mg | | | |
| | | | | |

| Inactive Ingredients | | | |
|---|----------|--|--|
| Ingredient Name | Strength | | |
| CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01Z NK31) | | | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | | | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | | | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | | | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | | | |

| Product Characteristics | | | | |
|-------------------------|-------|--------------|-------------|--|
| Color | WHITE | Score | no score | |
| Shape | OVAL | Size | 16mm | |
| Flavor | | Imprint Code | Mxeunic;600 | |
| Contains | | | | |

| F | Packaging | | | | | |
|---|----------------------|---|-------------------------|-----------------------|--|--|
| # | tem Code | Package Description | Marketing Start Date | Marketing End Date | | |
| 1 | NDC:51316- 070-68 | 4 in 1 CARTON | 02/09/2021 | | | |
| 1 | | 17 in 1 BLISTER PACK; Type 0: Not a Combination Product | | | | |

| Marketing Information | | | |
|-----------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| NDA | NDA021282 | 02/09/2021 | |
| | | | |

Labeler - CVS PHARMACY, INC (062312574)

| Establishment | | | | | |
|--|---------|-----------|----------------------------|--|--|
| Name | Address | ID/FEI | Business Operations | | |
| RECKITT BENCKISER HEALTHCARE INTERNATIONAL LTD | | 230780363 | MANUFACTURE(51316-070) | | |

Revised: 4/2021 CVS PHARMACY, INC