

SUNMARK MUCUS RELIEF - guaifenesin tablet, extended release
Strategic Sourcing Services LLC

Sunmark mucus relief

Guaifenesin Extended-Release Tablets 600 mg

ACTIVE INGREDIENT(in each extended-release tablet)

Guaifenesin 600 mg

PURPOSE

Expectorant

USE(S)

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

WARNING

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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 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 to 25°C (68 to 77°F)

INACTIVE INGREDIENTS

carbomer homopolymer, hypromellose, microcrystalline cellulose, povidone

QUESTIONS?

1-609-860-2600

Hours: 8am - 4pm, EST

You may also report side effects to this phone number.

PRINCIPAL DISPLAY PANEL

sunmark

COMPARE TO THE ACTIVE INGREDIENT IN MUCINEX[®] EXTENDED RELEASE 600 MG TABLETS

NDC 70677-0055-1

12 hour

mucus relief

Guaifenesin Extended-Release Tablets 600 mg

Expectorant

Relieves chest congestion

Thins and Loosens Mucus

40 Extended-Release Tablets



SUNMARK MUCUS RELIEF

guaifenesin tablet, extended release

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70677-0055 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 600 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| CARBOMER HO MO POLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM30 7FC) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29 V3WO) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D6 1U) | |

POVIDONE (UNI: FZ989GH94E)

Product Characteristics

| | | | |
|-----------------|---------|---------------------|----------|
| Color | WHITE | Score | no score |
| Shape | CAPSULE | Size | 22mm |
| Flavor | | Imprint Code | G233 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70677-0055-1 | 4 in 1 CARTON | 09/26/2019 | |
| 1 | | 10 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 |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA209215 | 07/22/2018 | |

Labeler - Strategic Sourcing Services LLC (116956644)

Revised: 9/2019

Strategic Sourcing Services LLC