GUAIFENESIN- guaifenesin tablet, extended release Safrel Pharmaceuticals, LLC.

Guaifenesin Extended-Release Tablets 1200mg

ACTIVE INGREDIENT(S)

Guaifenesin 1200 mg (for 1200 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

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 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.

PREGNANCY/BREASTFEEDING

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 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(For 600mg)
- adults and children 12 years of age and over: 1 tablet every 12 hours. Do not exceed 2 tablets in 24 hours.(For 1200mg)
- 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; hypromellos, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

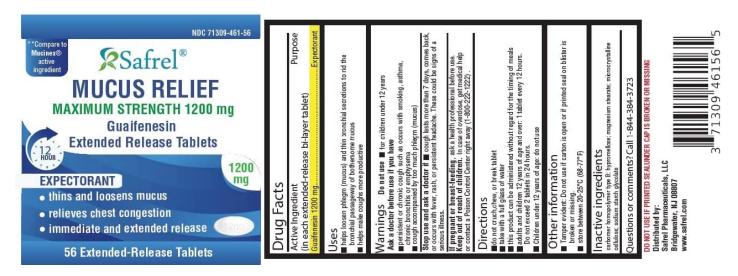
QUESTIONS OR COMMENTS

Contact 1-844-384-3723

Mon-Fri 8:00 AM EST to 5:00 PM PST.

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PRINCIPAL DISPLAY PANEL



guaifenesin tablet, extended release

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71309-461 |
| Route of Administration | ORAL | | |

| Active Ingredient/Act | ive Moiety | | |
|------------------------------|---------------------------------------|--------------------------|----------|
| In | ngredient Name | Basis of Strength | Strength |
| GUAIFENESIN (UNII: 495W745 | 51VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 1200 mg |

| Inactive Ingredients | | | |
|--|----------|--|--|
| Ingredient Name | Strength | | |
| CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208) | | | |
| HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4) | | | |
| SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D) | | | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | | | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | | | |

| Product Characteristics | | | |
|-------------------------|-------------------|--------------|----------|
| Color | white | Score | no score |
| Shape | OVAL (Elliptical) | Size | 22mm |
| Flavor | | Imprint Code | G;1200 |
| Contains | | | |

| Packaging | | | | |
|-----------|----------------------|---|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:71309-461- 56 | 56 in 1 BOTTLE; Type 0: Not a Combination Product | 06/29/2022 | |

| Marketing Information | | | |
|-----------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| ANDA | ANDA213420 | 12/18/2020 | |
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Labeler - Safrel Pharmaceuticals, LLC. (080566287)