

MUCUS RELIEF- guaifenesin 400 mg tablet
Advance Pharmaceutical Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Guaifenesin Caplets, 400 mg

Active ingredient (in each tablet)

Guaifenesin 400 mg

Purpose

Expectorant

Uses

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

Warnings

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 excessive phlegm (mucus)

KEEP OUT OF REACH OF CHILDREN

In case of overdose, get medical help or contact a Poison Control Center right away.

IN CASE OF PREGNANCY OR BREAST FEEDING SECTION

ask a health professional before use

stop use and ask a doctor

if cough lasts more than 7 days, comes back, or is accompanied by fever, rash or persistent headache. These could be signs of serious illness

Directions:

- **adults and children 12 years of age and over:** take 1 tablet every 4 hours with a full glass of water while symptoms persist. Do not exceed 6 doses in 24 hours.
- **children under 12 years:** do not use

- store at 15°-30°C (59°-86°F)
- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

Inactive ingredients

colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose, stearic acid, sodium starch glycolate

Questions or Comments

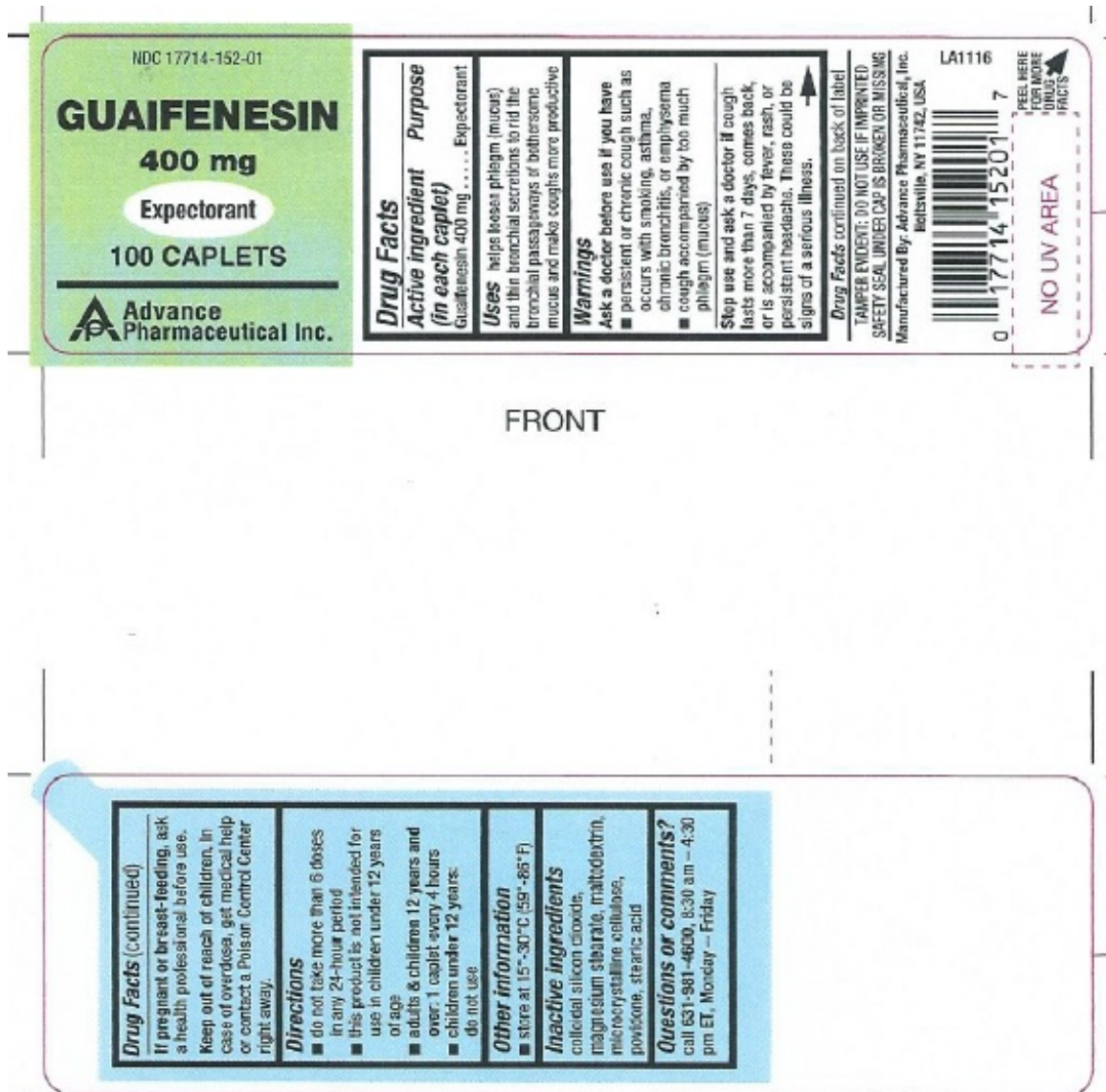
call 631-981-4600, 8.30 am-4.30 pm ET, Monday - Friday

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Principal Display Panel

Guaifenesin 400 mg... Expectorant

NDC-17714-152-01 100 tabs



MUCUS RELIEF

guaifenesin 400 mg tablet

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:17714-152 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 400 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| MALTODEXTRIN (UNII: 7CVR7L4A2D) | |
| POVIDONE (UNII: FZ989GH94E) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | white | Score | 2 pieces |
| Shape | OVAL | Size | 17mm |
| Flavor | | Imprint Code | AP;152 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:17714-152-01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 11/01/2016 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | 11/01/2016 | |

Labeler - Advance Pharmaceutical Inc. (078301063)**Registrant** - Advance Pharmaceutical Inc. (078301063)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|---------|-----------|------------------------|
| Advance Pharmaceutical Inc. | | 078301063 | manufacture(17714-152) |