

**GUAIFENESIN- guaifenesin tablet, extended release
Granules India Ltd**

Guaifenesin Extended-Release Tablets 600mg and 1200mg

ACTIVE INGREDIENT(S)

Guaifenesin 600 mg (for 600mg)

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 1-877-770-3183
Mon-Fri 8:00 AM EST to 5:00 PM PST.

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PRINCIPAL DISPLAY PANEL

Guaifenesin Extended-Release Tablet 1200 mg

Each Extended release tablet contains
Guaifenesin, USP 1200mg

Batch No. :XXXXXXX

No. of Units : 5x2000 no's

Mfg. Dt. : MM/YYYY

Gross Wt. : 00.000 Kg

Exp. Dt. : MM/YYYY

Tare Wt. : 00.000 Kg

Mfg.Lic.No. : 37/RR/AP/2003/F/R

Net Wt. : 00.000 Kg

NDC No. : 62207-569-93

Box No. : 000

Storage : Store between 20°C to 25°C (68°F to 77°F)

Caution : For repacking only.



(01)50362207569939(17)000000(10)XXXXXXX

Country of Origin: INDIA



(00)189036320000000004

FG Code: 700000002307

Guaifenesin Extended-Release Tablet 1200 mg

Each Extended release tablet contains
Guaifenesin, USP 1200mg

Batch No. :XXXXXXX

No. of Units : 2000 no's

Mfg. Dt. : MM/YYYY

Exp. Dt. : MM/YYYY

Mfg.Lic.No. : 37/RR/AP/2003/F/R

NDC No. : 62207-569-93

Storage : Store between 20°C to 25°C (68°F to 77°F)

Caution : For repacking only.

Country of Origin: INDIA

FG Code: 700000002307

Manufactured by:
Granules India Limited
Sy No. 160/A, 161/E, 162 & 174/A, Gogilapur Village, Dundigal – Gandimaisamma Mandal,
Medchal – Malkajgiri District – 500 043, India

Guaifenesin Extended-Release Tablets 600 mg

Pack Size: 270 x 20 tablets

Store between 20°C to 25°C (68° F to 77°F)

MLL No.: 37/RR/AP/2003/F/R

NDC: 62207-570-31

EXP: MM/YYYY LOT: XXXXXXX QTY: 0270



(01)50362207570317(17)000000(10)XXXXXXX



(00)189038320000000004

Sujani
Pillapalem

Digitally signed by
Sujani Pillapalem
Date: 2021.05.19
16:13:16 +05'30'

FG Code: 70000002430
Case No.: 0000

Manufactured by:
Granules India Limited
Sy No. 160/A, 161/E, 162 & 174/A, Gogilapur Village, Dundigal – Gandimaisamma Mandal,
Medchal – Malkajgiri District – 500 043, India

Guaifenesin Extended-Release Tablets 600 mg

Pack Size: 270 x 20 tablets

Store between 20°C to 25°C (68° F to 77°F)

MLL No.: 37/RR/AP/2003/F/R

NDC: 62207-570-31

EXP: MM/YYYY LOT: XXXXXXX QTY: 0270



(01)50362207570317(17)000000(10)XXXXXXX



(00)189038320000000004

Sujani
Pillapalem

Digitally signed by
Sujani Pillapalem
Date: 2021.05.19
16:13:33 +05'30'

FG Code: 70000002430
Case No.: 0000

Guaifenesin Extended-Release Tablet 600 mg

Each Extended release tablet contains

Guaifenesin, USP 600mg

Batch No. : XXXXXXX

Mfg. Dt. : MM/YYYY

Exp. Dt. : MM/YYYY

Mfg.Lic.No. : 37/RR/AP/2003/F/R

NDC No. : 62207-570-30

Storage : Store between 20°C to 25°C (68°F to 77°F)

Caution : For repacking only.



(01)50362207570300(17)000000(10)XXXXXXX

No. of Units : 5x4000 no's

Gross Wt. : 00.000 Kg

Tare Wt. : 00.000 Kg

Net Wt. : 00.000 Kg

Box No. : 000

Country of Origin: INDIA



(00)189038320000000004

GRANULES INDIA ADDRESS

FG Code: 70000002590

Guaifenesin Extended-Release Tablet 600 mg

Each Extended release tablet contains

Guaifenesin, USP 600mg

Batch No. :XXXXXXX

No. of Units : 4000 no's

Mfg. Dt. :MM/YYYY

Exp. Dt. :MM/YYYY

Mfg.Lic.No. :37/RR/AP/2003/F/R

NDC No. :62207-570-92

Storage : Store between 20°C to 25°C (68°F to 77°F)

Caution : For repacking only.

Country of Origin: INDIA

GRANULES INDIA ADDRESS

FG Code: 70000002590

Manufactured by:
Granules India Limited
Sy No. 160/A, 161/E, 162 & 174/A, Gagillapur Village, Dundigal – Gandimaisamma Mandal,
Medchal – Malkajgiri District – 500 043, India

Guaifenesin Extended-Release Tablets 1200 mg

Pack Size: 300 x 14 tablets

Store between 20 °C to 25 °C (68 ° F to 77° F)

M.L.No.: 37/RR/AP/2003/F/R

NDC: 62207-569-99

EXP: MM/YYYY

LOT: XXXXXXXX

QTY: 0300



(01)50362207569991(17)000000(10)XXXXXXXX



(00)18903832000000011

FG Code: 70000002590
Case No.: 0000

Manufactured by:
Granules India Limited
Sy No. 160/A, 161/E, 162 & 174/A, Gagillapur Village, Dundigal – Gandimaisamma Mandal,
Medchal – Malkajgiri District – 500 043, India

Guaifenesin Extended-Release Tablets 1200 mg

Pack Size: 300 x 14 tablets

Store between 20 °C to 25 °C (68 ° F to 77° F)

M.L.No.: 37/RR/AP/2003/F/R

NDC: 62207-569-99

EXP: MM/YYYY

LOT: XXXXXXXX

QTY: 0300



(01)50362207569991(17)000000(10)XXXXXXXX



(00)18903832000000011

FG Code: 70000002590
Case No.: 0000

GUAIFENESIN

guaifenesin tablet, extended release

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:62207-569 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| GUAIFENESIN (UNII: 495W7451VQ) (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:62207-569-99 | 4200 in 1 BAG; Type 0: Not a Combination Product | 02/01/2021 | |
| 2 | NDC:62207-569-93 | 5 in 1 BOX | 11/17/2021 | |
| 2 | | 2000 in 1 POUCH; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA213420 | 02/01/2021 | |

GUAIFENESIN

guaifenesin tablet, extended release

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:62207-570 |
| 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 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 | Size | 16mm |
| Flavor | | Imprint Code | G;600 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:62207-570-92 | 4000 in 1 BAG; Type 0: Not a Combination Product | 02/01/2021 | |
| 2 | NDC:62207-570-30 | 20000 in 1 BAG; Type 0: Not a Combination Product | 02/01/2021 | |
| 3 | NDC:62207-570-31 | 5400 in 1 BAG; Type 0: Not a Combination Product | 09/30/2021 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA213420 | 02/01/2021 | |

Labeler - Granules India Ltd (915000087)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------|---------|-----------|---|
| Granules India Ltd | | 918609236 | analysis(62207-569, 62207-570) , label(62207-569, 62207-570) , manufacture(62207-569, 62207-570) , pack(62207-569, 62207-570) |

Revised: 1/2023

Granules India Ltd