

GUAIFENESIN AND DEXTROMETHORPHAN HYDROBROMIDE- guaifenesin and dextromethorphan hydrobromide tablet
APNAR PHARMA LP

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 and Dextromethorphan Hydrobromide Tablets 400 +20 mg

Caution: do not use if imprinted seal under cap is broken or missing

Drug Facts

Active Ingredients (per tablet)

Guaifenesin USP..... 400 mg

Dextromethorphan Hydrobromide USP..... 20 mg

Purpose

Expectorant

Cough suppressant

Uses:

- Temporarily relieves cough due to minor throat and bronchial irritation as may occur with the common cold
- Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus
- Helps make coughs more productive.

WARNINGS

Do not use

- if you are now taking a prescription Monoamine Oxidase Inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before using this product.

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)

Stop use and ask a doctor if

- Symptoms are accompanied by fever, rash or persistent headache
- cough persists for more than 1 week or tends to recur
- A persistent cough may be a sign of a serious condition

If pregnant or breast-feeding, ask a healthcare professional before use.

Keep out of reach of children

In case of overdose, get medical help or contact poison control center immediately

Directions

- **Adults and children 12 years of age and over:** take 1 tablet every 4 hours as needed
- **Children 6 to 12 years of age:** take 1/2 tablet every 4 hours as needed
- **Children under 6 years of age:** consult a doctor.

Do not exceed 6 doses in 24 hour period or as directed by a doctor

Other Information

- store at 15°-30°C (59°-86°F)

Inactive Ingredients

Microcrystalline cellulose, Croscarmellose sodium, Povidone, silicon dioxide, magnesium stearate

Questions or concerns?

- 1-855-642-2594

Distributed by:

APNAR PHARMA LP

CHINO, CA, 91710

Rev.: 04/2022

APNAR PHARMA LP

NDC 24689-123-01

Guaifenesin and Dextromethorphan Hydrobromide Tablets 400 + 20mg- 20s tablets

Drug Facts

Active Ingredients (per tablet) Purpose
 Guaifenesin USP 400 mg.....Expectorant
 Dextromethorphan Hydrobromide
 USP 20 mg.....Cough Suppressant

Uses - Temporarily relieves cough due to minor throat and bronchial irritation as may occur with a common cold - helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus - helps make coughs more productive

Warnings

Do not use - if you are now taking prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease) or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains a MAOI, ask a doctor or pharmacist before using this product.

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)

Stop use and ask a doctor if - symptoms are accompanied by fever, rash or persistent headache

NDC 24689-123-01

Guaifenesin and Dextromethorphan Hydrobromide Tablets 400 +20 mg

Expectorant and Cough Suppressant

- Loosen & Relieves Chest Congestion
 - Control Cough
 - Immediate Release Tablets
- 20 Tablets



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Drug Facts (continue

- cough persist for more than 7 days
 A persistent cough may indicate a more serious condition.
 If pregnant or breast-feeding, consult your healthcare provider before using this product.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center at 1-800-422-4242.

Directions

- Adults and children 12 years of age and older: 2 tablets every 4 hours as needed.
 - Children 6 to under 12 years of age: 1 tablet every 4 hours as needed.
 - Children under 6 years of age: Do not use.
- Do not exceed 6 doses in a 24 hour period.

Other information

Inactive Ingredients
 Microcrystalline cellulose, croscarmellose sodium, povidone, silicon dioxide, and polyethylene glycol 400.

Unvarnished Area/
 For Batch no. 8
 (1.15 x 0.35)

APNAR PHARMA LP

NDC 24689-123-02

Guaifenesin and Dextromethorphan Hydrobromide Tablets 400 + 20mg- 500s tablets

Drug Facts

Active Ingredients (per tablet) Purpose
 Guaifenesin USP 400 mg.....Expectorant
 Dextromethorphan Hydrobromide USP 20 mg.....Cough Suppressant

Uses
 - Temporarily relieves cough due to minor throat and bronchial irritation as may occur with a common cold
 - helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus
 - helps make coughs more productive

Warnings

Do not use
 - if you are now taking prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease) or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains a MAOI, ask a doctor or pharmacist before using this product.

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)

Stop use and ask a doctor if
 - symptoms are accompanied by fever, rash or persistent headache
 - cough persist for more than 1 week or tends to recur
 - A persistent cough may be a sign of a serious condition

NDC 24689-123-02

Guaifenesin and Dextromethorphan Hydrobromide Tablets 400 + 20 mg

Expectorant & Cough Suppressant

- Loosen & Relieves Chest Congestion
 - Control Cough
 - Immediate Release Tablets
- 500 Tablets



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Drug Facts (continued)

- cough persist for more than 7 days
 In case of overdose, get medical help or contact a Poison Control Center at 1-800-422-4242.

Directions

- Adults and children 12 years of age and older: 2 tablets every 4 hours as needed.
 - Children 6 to under 12 years of age: 1 tablet every 4 hours as needed.
 - Children under 6 years of age: Do not use.
- Do not exceed 6 doses in a 24 hour period.

Other information
 - Store at 15° - 30°C (59° - 86° F) excursions permitted to 15° - 30°C (59° - 86° F) (see USP Controlled Room Temperature).

Inactive Ingredients
 Microcrystalline cellulose, croscarmellose sodium, povidone, silicon dioxide, and polyethylene glycol 400.

Questions or Concerns?
 • 1-855-642-2594

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 (2)

GUAIFENESIN AND DEXTROMETHORPHAN HYDROBROMIDE

guaifenesin and dextromethorphan hydrobromide tablet

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:24689-123 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------|-------------------|----------|
|-----------------|-------------------|----------|

| | | |
|---|----------------------------------|--------|
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 400 mg |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 20 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| POVIDONE K30 (UNII: U725QWY32X) | |
| WATER (UNII: 059QF0KO0R) | |
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |

Product Characteristics

| | | | |
|-----------------|---------|---------------------|----------|
| Color | white | Score | 2 pieces |
| Shape | CAPSULE | Size | 18mm |
| Flavor | | Imprint Code | LT13 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:24689-123-01 | 20 in 1 BOTTLE; Type 0: Not a Combination Product | 12/30/2022 | |
| 2 | NDC:24689-123-02 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 12/30/2022 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | 12/30/2022 | |

Labeler - APNAR PHARMA LP (079568229)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------------|---------|-----------|--|
| Apnar Pharma Private Limited | | 876730408 | analysis(24689-123) , manufacture(24689-123) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------|---------|-----------|------------------------------------|
| APNAR PHARMA LLP | | 118530917 | pack(24689-123) , label(24689-123) |