

GUAIFENESIN- guaifenesin 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 Tablets 400 mg

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

Drug Facts

Active Ingredient (per tablet)

Guaifenesin USP..... 400 mg

Purpose

Expectorant

Use

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

Warnings

Ask doctor before use if you have

- persistent or chronic cough, such as occurs with smoking, asthma, 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 health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a 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 a 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 : 24689-122-01

Guaifenesin Tablets 400mg-20's Tablets

<p>Drug Facts Caution: do not use if imprinted seal under cap is broken or missing</p> <p>Active Ingredient (per tablet) Purpose Guaifenesin USP 400 mg.....Expectorant</p> <p>Use ▪ helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus ▪ helps make coughs more productive</p> <p>Warnings Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ▪ persistent or chronic cough, such as occurs with smoking, asthma, chronic bronchitis or emphysema ▪ cough accompanied by excessive phlegm (mucus) <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ▪ symptoms are accompanied by fever, rash or persistent headache ▪ cough persist for more than 1 week or tends to recur <p>◀ A persistent cough may be a sign of a serious condition</p>	<p>NDC 24689-122-01</p> <p>Guaifenesin Tablets 400 mg Expectorant</p> <ul style="list-style-type: none"> ▪ Relieves Chest Congestion ▪ Thins and Loosens Mucus ▪ Immediate Release Tablets <p>20 Tablets</p>	<p>Drug Facts (continued)</p> <p>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</p> <p>Directions</p> <ul style="list-style-type: none"> ▪ Adults and children 12 years of age and over: take 1 tablet every 4 hours as needed ▪ Children 6 to under 12 years of age: take 1/2 tablet every 4 hours as needed ▪ Children under 6 years of age: consult a doctor <p>Do not exceed 6 doses in a 24 hour period or as directed by a doctor</p> <p>Other information ▪ Store at 15° - 30°C (59° - 86° F).</p> <p>Inactive Ingredients Microcrystalline cellulose, Croscarmellose sodium, povidone, silicon dioxide, magnesium stearate</p>
 <p>Distributed by: APNAR PHARMA LP CHINO, CA, 91710</p>	<p>Unvarnished Area/ Coding Area For Batch no. & Exp. Dt. (1.15 x 0.35 inches)</p>	<p>Rev.: 04/2022 Questions or Concerns? ▪ 1-855-642-2594</p> 

APNAR PHARMA LP

NDC : 24689-122-02

Guaifenesin Tablets 400mg-500's Tablets

Drug Facts

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

Active Ingredient (per tablet)

Guaifenesin USP 400 mg.....Expectorant

Purpose

Expectorant

Use

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

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

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

NDC 24689-122-02

Guaifenesin Tablets 400 mg

Expectorant

- Relieves Chest Congestion
- Thins and Loosens Mucus
- Immediate Release Tablets

500 Tablets



Distributed by:
APNAR PHARMA LP
CHINO, CA, 91710

Drug Facts (continued)

Directions

Adults and children 12 years of age and over	take 1 tablet every 4 hours as needed
Children 6 to under 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 a 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

Rev.: 04/2022

Unvarnished Area/ Coding Area
For Batch no. & Exp. Dt.
(2.8 x 0.8 inches)



GUAIFENESIN

guaifenesin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24689-122
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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
POVIDONE K30 (UNII: U725QWY32X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white (White to off White color)	Score	2 pieces
Shape	ROUND	Size	13mm
Flavor		Imprint Code	LT;12
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:24689-122-01	20 in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2022	
2	NDC:24689-122-02	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(24689-122) , manufacture(24689-122)

Establishment

Name	Address	ID/FEI	Business Operations
APNAR PHARMA LLP		118530917	pack(24689-122) , label(24689-122)

Revised: 1/2023

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