

GUAIFENESIN 400MG- guaifenesin tablet
Marlex Pharmaceuticals Inc

Guaifenesin 400mg

GUAIFENESIN400MG TABLETS

MarlexPharmaceuticals, Inc.

Drug Fact

Active ingredient (in each tablet)

Guaifenesin 400mg

Purpose

Expectorant

Guaifenesin 400 mg Tablets

Uses

helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageway of bothersome mucus and 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 too much phlegm (mucus)

Stop use and ask a doctor if

cough last more than 7 days, come back or is accompanied by fever, rash, or persistent headache. There could be signs of a serious illness.

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

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 right away.

Directions:

- Do not take more than 6 doses in any 24-hour period.
- This product is not intended for use in children under 12 years of age
- Adults & children 12 years and over: 1 to 2 tablets every 4 hours
- Children under 12 years: do not use

Other Information:

- Store at 15°C-30°C (59°F-86°F)

Inactive Ingredients:

Colloidal silicon dioxide, FD&C RED #40(Al-lake), magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, stearic acid

Manufactured for & Distributed by:

Marlex Pharmaceuticals, Inc.

New Castle, DE 19720

Rev: 02/19TCL

PRINCIPAL DISPLAY PANEL

NDC 10135-0682-30

Guaifenesin

400 mg

30 CAPLETS

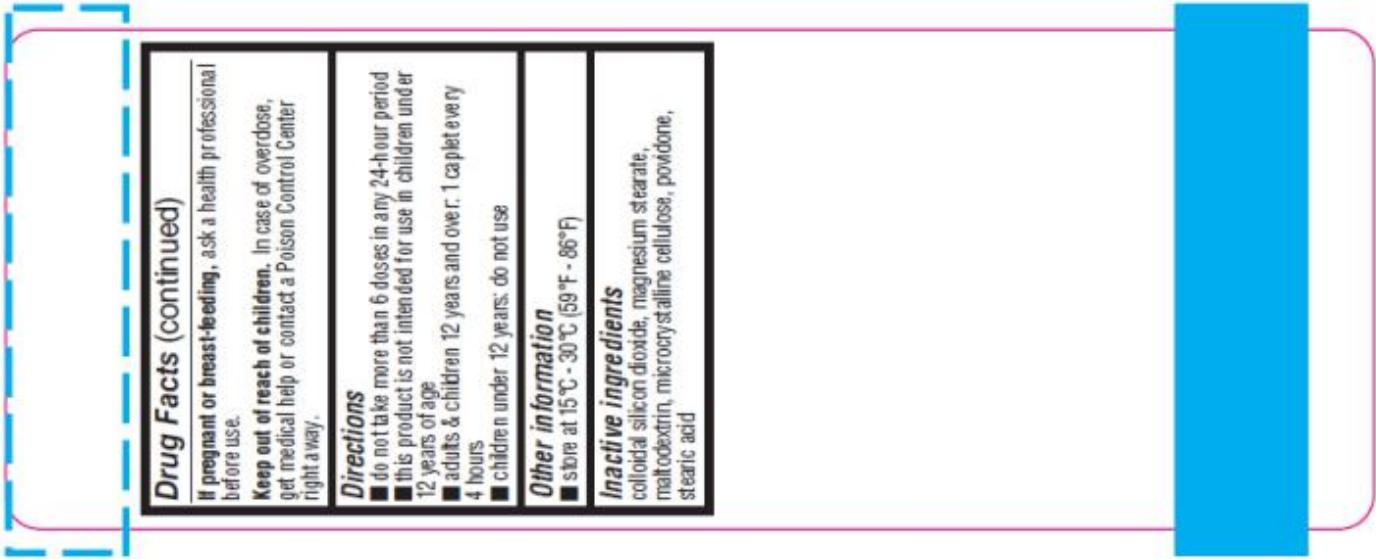


PRINCIPAL DISPLAY PANEL

NDC 10135-0682-60
Guaifenesin
400 mg
60 CAPLETS

NDC 10135-0682-60 MARLEX PHARMACEUTICALS, INC. Guaifenesin 400 mg 60 CAPLETS		Drug Facts Active ingredient (in each caplet) Purpose Guaifenesin 400 mg Expectorant Uses Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of both some mucus and 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 too much phlegm (mucus) 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 a serious illness. TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING Manufactured for/Distributed by: Marlex Pharmaceuticals, Inc. New Castle, DE 19720 Rev. 03/19 HP Peel Here For More Drug Facts Drug Facts (continued on back)
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Drug Facts (continued) 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 right away.	Directions ■ do not take more than 6 doses in any 24-hour period ■ this product is not intended for use in children under 12 years of age ■ adults & children 12 years and over: 1 caplet every 4 hours ■ children under 12 years: do not use	Other information ■ store at 15°C - 30°C (59°F - 86°F)	Inactive ingredients colloidal silicon dioxide, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, stearic acid
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GUAIFENESIN 400MG			
guaifenesin tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10135-682
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)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MALTODEXTRIN (UNII: 7CVR7L4A2D)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
POVIDONE (UNII: FZ989GH94E)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
Product Characteristics			
Color	white	Score	no score
Shape	CAPSULE (Caplet)	Size	10mm
Flavor		Imprint Code	G400
Contains			
Packaging			

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10135-682-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2019	
2	NDC:10135-682-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2019	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M012	03/01/2019	

Labeler -
Marlex Pharmaceuticals Inc (782540215)