

GUAIFENESIN 600 MG - guaifenesin 600 mg tablet
GUAIFENESIN 1200 MG - guaifenesin 1200 mg tablet
MARKSANS PHARMA LIMITED

Guaifenesin Extended-Release Tablets 600 mg and 1200 mg

OTC - ACTIVE INGREDIENT SECTION

For 600 mg:

Active ingredient (in each extended-release tablet)

Guaifenesin, USP 600 mg

For 1200 mg:

Active ingredient (in each extended-release tablet)

Guaifenesin, USP 1200 mg

OTC - PURPOSE SECTION

Purpose

Expectorant

INDICATIONS & USAGE SECTION

Uses

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

WARNINGS SECTION

OTC - DO NOT USE SECTION

Do not use

- for children under 12 years of age

OTC - ASK DOCTOR SECTION

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)

OTC - STOP USE SECTION

Stop use and ask a 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.

OTC - PREGNANCY OR BREAST FEEDING SECTION

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

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

DOSAGE & ADMINISTRATION SECTION

Directions

For 600 mg

- do not crush, chew, or break extended - release tablet
- take with a full glass of water
- this product can be administered without regard for the timing of meals
- adults and children 12 years of age and over: 1 or 2 extended - release tablets every 12 hours. Do not exceed 4 extended - release tablets in 24 hours.
- children under 12 years of age: do not use

For 1200 mg

- do not crush, chew, or break extended - release tablet
- take with a full glass of water
- this product can be administered without regard for the timing of meals
- adults and children 12 years of age and over: 1 extended - release tablet every 12 hours. Do not exceed 2 extended - release tablets in 24 hours.
- children under 12 years of age: do not use

STORAGE AND HANDLING SECTION

Other information

- store at 20-25°C (68-77°F)

INACTIVE INGREDIENT SECTION

Inactive ingredients colloidal silicon dioxide, copovidone, FD&C Blue No. 1 Aluminum lake, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone (K-30), sodium starch glycolate, stearic acid

OTC - QUESTIONS SECTION

Questions or comments?

Call **1-877-376-4271** (weekdays 9 AM to 5 PM)

You may also report side effects to this phone number.

Manufactured for:

Time-Cap Labs, Inc.

7 Michael Avenue,

Farmingdale,

NY 11735, USA

Manufactured by:

Marksans Pharma Ltd.

Plot No. L-82, L-83

Verna Indl. Estate

Verna, Goa-403722, India

PRINCIPAL DISPLAY PANEL

NDC: 25000-042-55

Guaifenesin Extended-Release Tablets 600 mg

20's count (2 x 10's blister) Carton

Drug Facts (continued)

- 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 occurs with fever, rash, or persistent headache. These could be signs of a serious illness.

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 (1-800-222-1222), right away.

Directions

- do not crush, chew, or break extended-release tablet
- take with a full glass of water
- this product can be administered without regard for the timing of meals
- adults and children 12 years of age and over: 1 or 2 extended-release tablets every 12 hours. Do not exceed 4 extended-release tablets in 24 hours.
- children under 12 years of age: do not use

Other information

- store at 20-25°C (68-77°F)

Inactive ingredients

colloidal silicon dioxide, copovidone, FD&C Blue No. 1 Aluminum lake, hypromellose, magnesium stearate, methocel K100, microcrystalline cellulose, povidone (K-30), sodium starch glycolate, stearic acid

Questions or comments?

Call 1-877-376-4271 (weekdays 9 AM to 5 PM) You may also report side effects to this phone number.

Adhesive Area

R10323

Varnish Omit Area

Lot No.:
Exp Date:



Manufactured for:
Time-Cap Labs, Inc.
7 Michael Avenue, Farmingdale,
NY 11735, USA

Manufactured by:
Marksans Pharma Ltd.
Plot No. L-82, L-83, Verna Indl. Estate,
Verna, Goa-403722, India
Mfg. Lic. No.:GO/DRUGS/515

Do not use

- for children under 12 years of age

Ask a doctor before use if you have

- persistent or chronic cough such as

Warnings

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

Uses

Guaifenesin, USP 600 mg.....Expectorant

Purpose
(in each extended-release tablet)

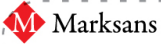
Guaifenesin, USP 600 mg.....Expectorant

Drug Facts

KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING

NDC 25000-042-01



Guaifenesin Extended-Release Tablets 600 mg

EXPECTORANT



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

20

EXTENDED-RELEASE TABLETS

NDC: 25000-042-01

Guaifenesin Extended-Release Tablets 600 mg


20's count Bottle Carton

NDC 25000-042-12


Marksans Compare to the active ingredient in Mucinex[®]

Guaifenesin Extended-Release Tablets 600 mg

EXPECTORANT



**THIS PACKAGE FOR HOUSEHOLDS
WITHOUT YOUNG CHILDREN**



ACTUAL SIZE

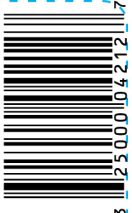
- ✓ Relieves Chest Congestion
- ✓ Thins and Loosens Mucus
- ✓ Immediate and Extended Release

500

EXTENDED-RELEASE
TABLETS

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING

<p>Drug Facts</p> <p>Active ingredient (in each extended-release tablet) Guaifenesin, USP 600 mg.....Expectorant</p> <p>Purpose</p> <p>Uses <ul style="list-style-type: none"> ■ helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive </p> <p>Warnings Do not use <ul style="list-style-type: none"> ■ for children under 12 years of age Ask a doctor before use if you have <ul style="list-style-type: none"> ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema ■ cough accompanied by too much phlegm (mucus) </p>	<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if <ul style="list-style-type: none"> ■ cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious illness.</p> <p>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 (1-800-222-1222) right away.</p> <p>Directions <ul style="list-style-type: none"> ■ do not crush, chew, or break extended-release tablet ■ take with a full glass of water ■ this product can be administered without regard for the timing of meals ■ adults and children 12 years of age and over: 1 or 2 extended-release tablets every 12 hours. Do not exceed 4 extended-release tablets in 24 hours. ■ children under 12 years of age: do not use </p>	<p>Drug Facts (continued)</p> <p>Other information <ul style="list-style-type: none"> ■ store at 20-25°C (68-77°F) </p> <p>Inactive ingredients colloidal silicon dioxide, copovidone, FD&C Blue No. 1 Aluminum lake, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone (K-30), sodium starch glycolate, stearic acid</p> <p>Questions or comments? Call 1-877-376-4271 (weekdays 9 AM to 5 PM) You may also report side effects to this phone number.</p> <p><small>*This product is not manufactured or distributed by RB Health US LLC, owner of the registered trademark Mucinex[®]. Manufactured for: Time-Cap Labs, Inc. 7 Michael Avenue, Farmingdale, NY 11735, USA Manufactured by: Marksans Pharma Ltd. Plot No. L-82, L-83, Verma Indl. Estate, Verma, Goa-403722, India Mfg. Lic. No.:GO/DRUGS/515 R10323</small></p>
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2500004212

Warnish Omit Area

Lot No.:
Exp. Date:

NDC: 25000-041-75

Guaifenesin Extended-Release Tablets 1200 mg

12's count (2 x 6's blister) Carton

Drug Facts (continued)

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 a 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.
- If pregnant or breast-feeding, ask a health professional before use. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Drug Facts (continued)

Directions

- do not crush, chew, or break extended - release tablet
- take with a full glass of water
- this product can be administered without regard for the timing of meals
- adults and children 12 years of age and over: 1 extended - release tablet every 12 hours. Do not exceed 2 extended - release tablets in 24 hours.
- children under 12 years of age: do not use

Other information

- store at 20-25°C (68-77°F)

Inactive ingredients

colloidal silicon dioxide, copovidone, FD&C Blue No. 1 Aluminum lake, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone (K-30), sodium starch glycolate, stearic acid

Questions or comments?
Call 1-877-376-4271 (weekdays 9 AM to 5 PM) You may also report side effects to this phone number.

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPEN OR IF PRINTED SEAL ON BLISTER IS BROKEN OR MISSING

This product is not manufactured or distributed by RB Health US LLC, owner of the registered trademark Mucinex®.

3 1250001041751 5

Manufactured for: Time-Cap Labs, Inc. 7 Michael Avenue, Farmingdale, NY 11735, USA
Manufactured by: Marksans Pharma Ltd. Plot No. L-82, L-83, Verna Indl. Estate, Verna, Goa-403722, India. Mfg. Lic. No. G00/DPH/US/515 R10323

Drug Facts (continued)

Active ingredient
(in each extended-release tablet)

Guaifenesin, USP 1200 mg.....Expectorant

Purpose

Uses

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

Drug Facts (continued)

3 1250001041751 5

Drug Facts (continued)

Directions

- do not crush, chew, or break extended - release tablet
- take with a full glass of water
- this product can be administered without regard for the timing of meals
- adults and children 12 years of age and over: 1 extended - release tablet every 12 hours. Do not exceed 2 extended - release tablets in 24 hours.
- children under 12 years of age: do not use

Other information

- store at 20-25°C (68-77°F)

Inactive ingredients

colloidal silicon dioxide, copovidone, FD&C Blue No. 1 Aluminum lake, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone (K-30), sodium starch glycolate, stearic acid

Questions or comments?
Call 1-877-376-4271 (weekdays 9 AM to 5 PM) You may also report side effects to this phone number.

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3 1250001041751 5

Manufactured for: Time-Cap Labs, Inc. 7 Michael Avenue, Farmingdale, NY 11735, USA
Manufactured by: Marksans Pharma Ltd. Plot No. L-82, L-83, Verna Indl. Estate, Verna, Goa-403722, India. Mfg. Lic. No. G00/DPH/US/515 R10323

NDC: 25000-041-12

Guaifenesin Extended-Release Tablets 1200 mg

500's count Bottle Label

NDC 25000-041-12

Marksans Compare to the active ingredient in Maximum Strength Mucinex®†

MAXIMUM STRENGTH

Guaifenesin

Extended-Release Tablets 1200 mg

EXPECTORANT

12 HOUR

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

- ✓ Relieves Chest Congestion
- ✓ Thins and Loosens Mucus
- ✓ Immediate and Extended Release

ACTUAL SIZE

500 EXTENDED-RELEASE TABLETS

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING

Drug Facts	Drug Facts (continued)	Drug Facts (continued)
<p>Active ingredient (in each extended-release tablet) Guaifenesin, USP 1200 mg.....Expectorant</p> <p>Purpose</p> <p>Uses</p> <ul style="list-style-type: none"> ■ helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive <p>Warnings</p> <p>Do not use</p> <ul style="list-style-type: none"> ■ for children under 12 years of age <p>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 too much phlegm (mucus) <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. 	<p>These could be signs of a serious illness.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.</p> <p>Directions</p> <ul style="list-style-type: none"> ■ do not crush, chew, or break extended-release tablet ■ take with a full glass of water ■ this product can be administered without regard for the timing of meals ■ adults and children 12 years of age and over: 1 extended-release tablet every 12 hours. Do not exceed 2 extended-release tablets in 24 hours. ■ children under 12 years of age: do not use <p>Other information</p> <ul style="list-style-type: none"> ■ store at 20-25°C (68-77°F) <p>Inactive ingredients colloidal silicon dioxide, copovidone, FD&C Blue No. 1 Aluminum lake, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose,</p>	<p>povidone (K-30), sodium starch glycolate, stearic acid</p> <p>Questions or comments? Call 1-877-376-4271 (weekdays 9 AM to 5 PM) You may also report side effects to this phone number.</p> <p>†This product is not manufactured or distributed by RB Health US LLC, owner of the registered trademark Mucinex®.</p> <p>Manufactured for: Time-Cap Labs, Inc. 7 Michael Avenue, Farmingdale, NY 11735, USA</p> <p>Manufactured by: Marksans Pharma Ltd. Plot No. L-82, L-83, Verna Indl. Estate, Verna, Goa-403722, India</p> <p>Mfg. Lic. No.:GO/DRUGS/515 R10323</p>

Lot No.:
Exp. Date:

Varnish Omit Area

GUAIFENESIN 600 MG

guaifenesin 600 mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:25000-042
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
COPOVIDONE K25-31 (UNII: D9C330MD8B)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	

Product Characteristics

Color	WHITE (Blue and White)	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	42
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25000-042-55	2 in 1 CARTON	08/23/2023	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:25000-042-01	1 in 1 CARTON	08/23/2023	
2		20 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:25000-042-12	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/23/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA217780	08/23/2023	

GUAIFENESIN 1200 MG

guaifenesin 1200 mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:25000-041
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
POVIDONE K30 (UNII: U725QWY32X)	

SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
COPOVIDONE K25-31 (UNII: D9C330MD8B)	

Product Characteristics

Color	WHITE (Blue and White)	Score	no score
Shape	CAPSULE	Size	22mm
Flavor		Imprint Code	41
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25000-041-75	2 in 1 CARTON	08/23/2023	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:25000-041-12	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/23/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA217780	08/23/2023	

Labeler - MARKSANS PHARMA LIMITED (925822975)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	MANUFACTURE(25000-041, 25000-042)

Revised: 8/2023

MARKSANS PHARMA LIMITED