

**GUAIFENESIN AND PSEUDOEPHEDRINE HCL- guaifenesin and pseudoephedrine hcl tablet, extended release
Granules India Ltd**

Guaifenesin and Pseudoephedrine HCl Extended-Release Tablets 600 mg and 60 mg; 1200 mg and 120 mg

Drug Facts

ACTIVE INGREDIENTS

(in each extended-release tablet)

Guaifenesin USP, 600 mg

Pseudoephedrine HCL USP, 60 mg

Guaifenesin USP, 1200 mg

Pseudoephedrine HCL USP, 120 mg

PURPOSES

Expectorant

Nasal Decongestant

USES

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves nasal congestion due to:
 - common cold
 - hay fever
 - upper respiratory allergies
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage

- temporarily relieves sinus congestion and pressure

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 taking this product.

ASK A DOCTOR BEFORE USE IF YOU HAVE

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough accompanied by too much phlegm (mucus)

WHEN USING THIS PRODUCT

- do not use more than directed

STOP USE AND ASK A DOCTOR IF

- you get nervous, dizzy, or sleepless
- symptoms do not get better within 7 days, come back or occur with a 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 Centre 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 and older:

For 600mg and 60mg: 2 tablets every 12 hours; not more than 4 tablets in 24 hours

For 1200mg and 120mg: 1 tablet every 12 hours; not more than 2 tablets in 24 hours

- 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, cellulose microcrystalline, hypromellose, lake of FD&C yellow 6, magnesium stearate, sodium starch glycolate Type A

QUESTIONS OR COMMENTS

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

You may also report side effects to this phone number.

Keep the carton.

It contains important information. See end panel for expiration date.

Manufactured By:

Granules India Limited

Hyderabad - 500 081, INDIA

MADE IN INDIA

Distributed By:

Granules USA, Inc.

Parsippany, NJ 07054

PRINCIPAL DISPLAY PANEL

<p>MAXIMUM STRENGTH NDC 62207-828-71 Guaifenesin and Pseudoephedrine HCl Extended-Release Tablet 1200 mg and 120 mg Expectorant & Nasal Decongestant Mfg. by: Granules India Limited Made in India Push tablet through foil LOT# EXP. DATE:</p> <p>ML No.: 37FR/AP/2003/FR</p>	<p>MAXIMUM STRENGTH NDC 62207-828-71 Guaifenesin and Pseudoephedrine HCl Extended-Release Tablet 1200 mg and 120 mg Expectorant & Nasal Decongestant Mfg. by: Granules India Limited Made in India Push tablet through foil LOT# EXP. DATE:</p> <p>ML No.: 37FR/AP/2003/FR</p>	<p>MAXIMUM STRENGTH NDC 62207-828-71 Guaifenesin and Pseudoephedrine HCl Extended-Release Tablet 1200 mg and 120 mg Expectorant & Nasal Decongestant Mfg. by: Granules India Limited Made in India Push tablet through foil LOT# EXP. DATE:</p> <p>ML No.: 37FR/AP/2003/FR</p>	<p>MAXIMUM STRENGTH NDC 62207-828-71 Guaifenesin and Pseudoephedrine HCl Extended-Release Tablet 1200 mg and 120 mg Expectorant & Nasal Decongestant Mfg. by: Granules India Limited Made in India Push tablet through foil LOT# EXP. DATE:</p> <p>ML No.: 37FR/AP/2003/FR</p>	<p>MAXIMUM STRENGTH NDC 62207-828-71 Guaifenesin and Pseudoephedrine HCl Extended-Release Tablet 1200 mg and 120 mg Expectorant & Nasal Decongestant Mfg. by: Granules India Limited Made in India Push tablet through foil LOT# EXP. DATE:</p> <p>ML No.: 37FR/AP/2003/FR</p>
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Drug Facts		Drug Facts (continued)	
Active Ingredients (In each extended-release tablet) Guaifenesin USP, 1200 mg.....Expectorant Pseudoephedrine HCl USP, 120 mg.....Nasal Decongestant	Purposes	<ul style="list-style-type: none"> thyroid disease diabetes trouble urinating due to an enlarged prostate gland persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema cough accompanied by too much phlegm (mucus) 	
Uses		When using this product	
<ul style="list-style-type: none"> helps loosen phlegm (mucus) and thin bronchial secretions to let the bronchial passageways of both the nose and throat work better temporarily relieves nasal congestion due to: <ul style="list-style-type: none"> common cold hay fever upper respiratory allergies temporarily restores freer breathing through the nose promotes nasal and/or sinus drainage temporarily relieves sinus congestion and pressure 		<ul style="list-style-type: none"> do not use more than directed 	
Warnings		Stop use and ask a doctor if	
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 taking this product.		<ul style="list-style-type: none"> you get nervous, dizzy, or sleepless symptoms do not get better within 7 days, come back or occur with a fever, rash, or persistent headache. These could be signs of a serious illness. 	
Ask a doctor before use if you have		If pregnant or breast-feeding, ask a health professional before use.	
<ul style="list-style-type: none"> heart disease high blood pressure 		<ul style="list-style-type: none"> Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-325-1232). 	
		Directions	
		<ul style="list-style-type: none"> 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 and older: 1 tablet every 12 hours; not more than 2 tablets in 24 hours children under 12 years of age: do not use 	

Un varnish coding details

Drug Facts (continued)	<p>Mucinex[®] D is a registered trademark of Reichle Benzonier LLC.</p> <p>Manufactured By: Granules India Limited, Hyderabad - 500 081, INDIA</p> <p>Distributed By: Granules USA, Inc., Parsippany, NJ 07054</p> <p>MADE IN INDIA</p> <p>37/PRIAP/0003/FIR</p>
Other information	
<ul style="list-style-type: none"> Keep this and all other medicines out of the reach of children. See how to use part for expiries date. Keep the cap on. If contains in part information. See how to use part for expiries date. 	
Inactive ingredients	
carboxymethylcellulose sodium salt, croscarmellose sodium, hydroxypropyl methylcellulose, polyethylene glycol 400, polyethylene glycol 6000, polyethylene glycol 8000, polyethylene glycol 1000, polyethylene glycol 1500, polyethylene glycol 2000, polyethylene glycol 3000, polyethylene glycol 4000, polyethylene glycol 6000, polyethylene glycol 8000, polyethylene glycol 10000, polyethylene glycol 15000, polyethylene glycol 20000, polyethylene glycol 30000, polyethylene glycol 40000, polyethylene glycol 60000, polyethylene glycol 80000, polyethylene glycol 100000, polyethylene glycol 150000, polyethylene glycol 200000, polyethylene glycol 300000, polyethylene glycol 400000, polyethylene glycol 600000, polyethylene glycol 800000, polyethylene glycol 1000000	
Questions or comments?	
Contact 1-877-776-3182 Mon-Fri 9:00 AM EST to 5:00 PM PST. You may also report side effects to this phone number.	



2020090000

NDC 62207-828-71

MAXIMUM STRENGTH

Guaifenesin and Pseudoephedrine Hydrochloride Extended-Release Tablets

1200 mg and 120 mg

Expectorant & Nasal Decongestant

70 (7x10) Extended-Release Tablets

12HR

- Clears Nasal/Sinus Congestion
- Thins and Loosens Mucus
- Immediate and Extended Release

NDC 62207-828-71

MAXIMUM STRENGTH

Guaifenesin and Pseudoephedrine Hydrochloride Extended-Release Tablets

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Expectorant & Nasal Decongestant

70 (7x10) Extended-Release Tablets

MAXIMUM STRENGTH

Guaifenesin and Pseudoephedrine Hydrochloride Extended-Release Tablets

1200 mg and 120 mg

Expectorant & Nasal Decongestant

70 (7x10) Extended-Release Tablets



Guaifenesin and Pseudoephedrine HCl Extended-Release Tablet (600 mg and 60 mg)
Expectorant & Nasal Decongestant
Mfg. by: Granules India Limited
Made in India
Push tablet through foil
LOT#
EXP. DATE:



Guaifenesin and Pseudoephedrine HCl Extended-Release Tablet (600 mg and 60 mg)
Expectorant & Nasal Decongestant
Mfg. by: Granules India Limited
Made in India
Push tablet through foil
LOT#
EXP. DATE:



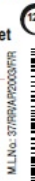
Guaifenesin and Pseudoephedrine HCl Extended-Release Tablet (600 mg and 60 mg)
Expectorant & Nasal Decongestant
Mfg. by: Granules India Limited
Made in India
Push tablet through foil
LOT#
EXP. DATE:



Guaifenesin and Pseudoephedrine HCl Extended-Release Tablet (600 mg and 60 mg)
Expectorant & Nasal Decongestant
Mfg. by: Granules India Limited
Made in India
Push tablet through foil
LOT#
EXP. DATE:



Guaifenesin and Pseudoephedrine HCl Extended-Release Tablet (600 mg and 60 mg)
Expectorant & Nasal Decongestant
Mfg. by: Granules India Limited
Made in India
Push tablet through foil
LOT#
EXP. DATE:



Guaifenesin and Pseudoephedrine HCl Extended-Release Tablet (600 mg and 60 mg)
Expectorant & Nasal Decongestant
Mfg. by: Granules India Limited
Made in India
Push tablet through foil
LOT#
EXP. DATE:



Guaifenesin and Pseudoephedrine HCl Extended-Release Tablet (600 mg and 60 mg)
Expectorant & Nasal Decongestant
Mfg. by: Granules India Limited
Made in India
Push tablet through foil
LOT#
EXP. DATE:



Guaifenesin and Pseudoephedrine HCl Extended-Release Tablet (600 mg and 60 mg)
Expectorant & Nasal Decongestant
Mfg. by: Granules India Limited
Made in India
Push tablet through foil
LOT#
EXP. DATE:



Guaifenesin and Pseudoephedrine HCl Extended-Release Tablet (600 mg and 60 mg)
Expectorant & Nasal Decongestant
Mfg. by: Granules India Limited
Made in India
Push tablet through foil
LOT#
EXP. DATE:



Guaifenesin and Pseudoephedrine HCl Extended-Release Tablet (600 mg and 60 mg)
Expectorant & Nasal Decongestant
Mfg. by: Granules India Limited
Made in India
Push tablet through foil
LOT#
EXP. DATE:





GUAIFENESIN AND PSEUDOEPHEDRINE HCL

guaifenesin and pseudoephedrine hcl tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62207-828
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	1200 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

Inactive Ingredients	
Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6130)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
HYPROMELLOSE 2910 (10000 MPA.S) (UNII: 0HO1H52958)	

Product Characteristics			
Color	orange (Light orange and orange colored)	Score	no score
Shape	OVAL	Size	22mm
Flavor		Imprint Code	GP;1200
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-828-71	7 in 1 CARTON	06/01/2023	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA216082	06/01/2023	

GUAIFENESIN AND PSEUDOEPHEDRINE HCL

guaifenesin and pseudoephedrine hcl tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62207-827
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	600 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	60 mg

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6I30)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01Z NK31)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
HYPROMELLOSE 2910 (10000 MPA.S) (UNII: 0HO1H52958)	

Product Characteristics

Color	orange (Light orange and orange colored)	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	GP;600
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-827-72	9 in 1 CARTON	06/01/2023	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA216082	06/01/2023	

Labeler - Granules India Ltd (915000087)