GUAIFENESIN- guaifenesin tablet
REMEDYREPACK INC.

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.

Major 44-588

Active ingredient (in each immediate-release tablet)

Guaifenesin 200 mg

Purpose

Expectorant

Uses

helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways 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 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 right away.

Directions

- **do not exceed 6 doses in 24 hours**
- take with a full glass of water

adults and children 12 years of age and over	1 to 2 tablets every 4 hours
children 6 to under 12 years of age	½ to 1 tablet every 4 hours
children under 6 years of age	consult a physician

Other information

- store at 25ºC (77ºF); excursions permitted between 15º-30ºC (59º-86ºF)
- use by expiration date on package

Inactive ingredients

FD&C red #40 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, silica gel, sodium starch glycolate, stearic acid

Questions or comments?

(800) 616-2471

DRUG: Guaifenesin

GENERIC: Guaifenesin

DOSAGE: TABLET

ADMINSTRATION: ORAL

NDC: 49349-511-02

COLOR: pink

SHAPE: ROUND

SCORE: No score

SIZE: 10 mm

IMPRINT: 44;588

PACKAGING: 30 in 1 BLISTER PACK

ACTIVE INGREDIENT(S):

- GUAIFENESIN 200mg in 1

INACTIVE INGREDIENT(S):

- FD&C RED NO. 40
- MAGNESIUM STEARATE
- STEARIC ACID
- POVIDONE
- CELLULOSE, MICROCRYSTALLINE
- MALTODEXTRIN
- SILICON DIOXIDE

Guaifenesin

200 mg Tablet

QTY: 30

ID #: 44;588
NDC #: 49349-0511-02
LOT #:
MFG: Major Pharma, Livonia, MI 48150

Expires:
Shape: Round
Ref #: 00904-5154-60

NOT FOR RETAIL SALE

Directions For Use: See Package Insert

Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) [See USP]

Repackaged by:
RemedyRepack Inc., Indiana, PA 15701, 1-724-465-8762

GUAIFENESIN

guaifenesin tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49349-511(NDC:0904-5154)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

Inactive Ingredients	
Ingredient Name	**Strength**
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics			
Color	pink (dark)	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	44;588
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49349-511-02	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	08/12/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/12/2010	

Labeler - REMEDYREPACK INC. (829572556)

Revised: 8/2017 REMEDYREPACK INC.