

MUCOSA- guaifenesin tablet
Unit Dose Services

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.

 Each immediate release tablet contains: Guaifenesin 400 mg

PURPOSE: EXPECTORANT

Keep Out of Reach of Children: In case of overdose, get medical help or contact a Poison Control Center

Silicon Dioxide, Magnesium Stearate, Maltodextrin, Cellulose, Microcrystalline, Povidone, Sodium Starch Glycolate, Stearic Acid

Adults and children 12 years of age and older, take 1 tablet every 4 hours with a full glass of water while symptoms persist. Do not exceed 6 doses in 24 hours. Children under 12 years of age do not use

Helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive to rid the bronchial passageway of bothersome mucus.

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)

HOW SUPPLIED

Product: 50436-6232

NDC: 50436-6232-2 60 TABLET in a BOTTLE

MUCUS RELIEF (GUAIFENESIN) TABLET

NDC: 50436-6232-2 MUCUS RELIEF (Guaifenesin) 400 MG / 60 TAB		Rev. 2 EXPECTORANT IMMEDIATE RELEASE - Alleviates Chest Congestion -Loosens Mucus <small>Dist. by: Major Pharmaceuticals, Livonia, MI 48150 USA</small>	<small>Directions: Adults and children 12 years of age and older: Take one tablet every 4 hours with a full glass of water while symptoms persist. Do not exceed 6 doses in 24 hours. Children under 12 years of age: do not use</small>
DRUG FACTS Active Ingredient (in each immediate-release tablet) Purpose Guaifenesin 400 mg Expectorant		Inactive Ingredients: colloidal silicon dioxide, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, silicon dioxide, sodium starch glycolate, stearic acid.	
USES Helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive to rid the bronchial passageway of bothersome mucus.		NDC: 50436-6232-2 400 MG / 60 TAB DRUG: MUCUS RELIEF (Guaifenesin) LOT: XXXXX EXP: XX/XX/XX	
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) When using this product: -Do not exceed recommended dosage. - Do not use for more than 7 days		Other Information: Store at 25° C (77° F) excursions permitted between 15° and 30° C (59° - 86° F). Keep in a dry place and do not expose to excessive heat.	
<small>Stop use and ask a doctor if: Cough lasts for more than 7 days, recurs, or is accompanied by fever, rash, or persistent headache. These could be signs 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 a Poison Control Center right away. Pkg. by: Unit Dose Services, LLC Dania, FL 33004</small>		LOT: XXXXX EXP: XX/XX/XX MFG NDC: 0904-6232-52 MFG LOT: XXXXXX	NDC: 50436-6232-2 400 MG / 60 TAB DRUG: MUCUS RELIEF (Guaifenesin) LOT: XXXXX EXP: XX/XX/XX

MUCOSA

guaifenesin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50436-6232(NDC:49483-272)
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)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	2 pieces
Shape	ROUND	Size	12mm
Flavor		Imprint Code	TCL272
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50436-6232-2	60 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/16/2012	

Labeler - Unit Dose Services (831995316)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 7/2017

Unit Dose Services