MUCUS RELIEF- guaifenes in tablet Clinical Solutions Wholes ale

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.

Mucus Relief 400mg

ACTIVE INGREDIENT: 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 right away

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)

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.

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

Principal Display Panel



Principal Display Panel



Principal Display Panel



MUCUS RELIEF

guaifenesin tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58118-9896(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 DIO XIDE (UNII: ETJ7Z6XBU4)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MALTO DEXTRIN (UNII: 7CVR7L4A2D)				
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)				

PO VIDONES (UNII: FZ989GH94E)

SO DIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)

STEARIC ACID (UNII: 4ELV7Z65AP)

Product Characteristics			
Color	white	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	TCL272
Contains			

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:58118-9896-3	30 in 1 BOTTLE, PLASTIC			
2	NDC:58118-9896-6	60 in 1 BOTTLE, PLASTIC			
3	NDC:58118-9896-9	90 in 1 BOTTLE, PLASTIC			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/23/2012	

Labeler - Clinical Solutions Wholesale (078710347)

Registrant - Clinical Solutions Wholesale (078710347)

Establishment				
Name	Address	ID/FEI	Business Operations	
Clinical Solutions Wholesale		078710347	REPACK(58118-9896), RELABEL(58118-9896)	

Revised: 11/2013 Clinical Solutions Wholesale