GUIAFENESIN - guiafenesin tablet
Sunrise Pharmaceutical 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.

Guaifenesin 400 mg Expectorant

OTC - ACTIVE INGREDIENT

Guaifenesin 400 mg.

OTC - PURPOSE

Expectorant.

INDICATIONS AND USAGE

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

WARNINGS

Ask a doctor before use if you have

Cough that lasts or chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema.

Cough accompanied by too much phlegm (mucus)

OTC - STOP USE AND ASK A DOCTOR IF

Cough lasts for more than 7 days, comes back, or occurs with fever, rash or persistent headache. These could be signs of a serious illness.

OTC – IF PREGNANT OR BREAST FEEDING

Ask a health professional before use.

OTC - KEEP OUT OF REACH OF CHILDREN

In case of overdose, get medical help or contact a Poison Control Center right away.

DIRECTIONS

Take with a glass of water

Adults and children 12 years and over	1 tablet every 4 hour. Max 6 doses
Children 6 to under 12 years	Do not use
Children under 6 years	Do not use

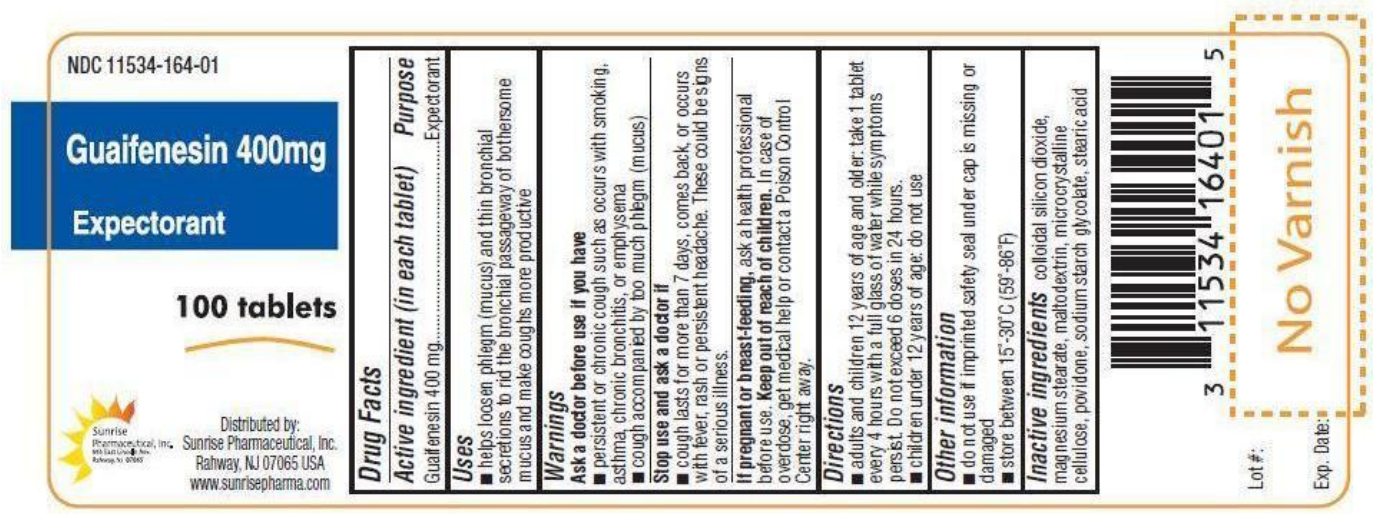
OTHER INFORMATION

Store at 15(-30(C(59(-86(F)

INACTIVE INGREDIENT

Colloidal silicon dioxide, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, sodium starch glycolate, stearic acid.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



GUIAFENESIN

guiafenesin tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11534-164
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)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	ROUND	**Size**	13mm
Flavor		**Imprint Code**	TCL;272
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11534-164-01	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/08/2005	

Labeler - Sunrise Pharmaceutical Inc (168522378)

Registrant - Sunrise Pharmaceutical Inc (168522378)

Revised: 7/2013 Sunrise Pharmaceutical Inc