

**GUAIFENESIN 400MG CAPLETS- guaifenesin tablet**  
**Gendose Pharmaceuticals, LLC**

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**GENDOSE - GUAIFENESIN 400 mg CAPLETS (77333-360)**

**ACTIVE INGREDIENT (IN EACH CAPLET)**

GUAIFENESIN 400MG

**PURPOSE**

EXPECTORANT

**USES**

- HELPS LOOSEN PHLEGM (MUCUS) AND THIN BRONCHIAL SECRETIONS TO RID THE BRONCHIAL PASSAGEWAY OF BOTHERSOME MUCUS.
- HELPS MAKE COUGHS MORE PRODUCTIVE

**WARNINGS**

ASK DOCTOR BEFORE USE IF YOU HAVE:

- PERSISTENT OR CHRONIC COUGH SUAH AS OCCURS WITH SMOKING, ASTHMA, CHRONIC BRONCHITIS OR EMPHASEMA (MUCUS)
- COUGH ACCOMPANIED BY EXCESSIVE PHLEGM

WHEN USING THIS PRODUCT

- DO NOT EXCEED RECOMMENDED DOSAGE
- DO NOT USE FOR MORE THAN 7 DAYS

STOP USE AND ASK A DOCTOR IS

- 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 HEALTH PROFESSIONAL BEFORE USE.

KEEP OUT OF REACH OF CHILDREN. IN CASE OF OVERDOSE, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER (1-800-222-1222) IMMEDIATELY.

**DIRECTIONS**

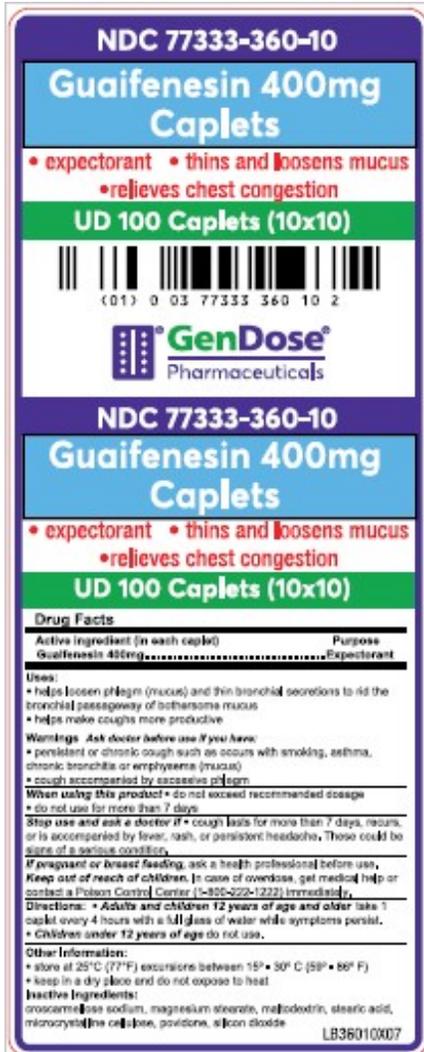
- **ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER** TAKE 1 CAPLET EVERY 4 HOURS WITH A FULL GLASS OF WATER WHILE SYMPTOMS PERSIST.
- **CHILDREN UNDER 12 YEARS OF AGE** DO NOT USE.

**OTHER INFORMATION**

- STORE AT 25°C (77°F) EXCURSIONS BETWEEN 15° - 30° C (59° - 86°F)
- KEEP IN A DRY PLACE AND DO NOT EXPOSE TO HEAT

## INACTIVE INGREDIENTS

CROSCARMELOSE SODIUM, MAGNESIUM STEARATE, MALTODEXTRIN, STEARIC ACID, MICROCRYSTALLINE CELLULOSE, POVIDONE, SILICON DIOXIDE



## GUAIFENESIN 400MG CAPLETS

guaifenesin tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77333-360
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL (CAPLET)	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	G400
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77333-360-10	100 in 1 BOX	09/02/2022	
1	NDC:77333-360-25	1 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
OTC Monograph Drug	M012	09/02/2022	

**Labeler** - Gendose Pharmaceuticals, LLC (080257510)

## Establishment

Name	Address	ID/FEI	Business Operations
ELYSIUM PHARMACEUTICALS LIMITED		915664486	manufacture(77333-360)

Revised: 1/2026

Gendose Pharmaceuticals, LLC