

**COUGH OUT- guaifenesin liquid**  
**Efficient Laboratories 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.*

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**Cough Out**

**Active Ingredient: (In each teaspoonful 5 mls)                      Purpose**

Guaifenesin 100 mg (USP).....Expectorant

**Purpose** Expectorant

**Uses**

Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus.

**Warnings**

**Do not exceed recommended dosage**

**Ask a doctor before use if you have**

- a cough that is accompanied by excessive phlegm (mucus)
- a persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema.

**Stop use and ask a doctor if**

- cough persists for more than 1 week, tends to recur, or is accompanied by a fever, rash, or persistent headach. A persistent cough may be a sign of a serious condition.

**Keep Out of Reach of Children.**

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

**If pregnant or breast-feeding,**ask a health professional before use.

**Directions:**

Shake well immediately before use.

Do not exceed 6 doses in any 24 hour period.

Adults and Children 12 years and over - 10 ml (2 tsps) every 4 hours

Children 6 to under 12 years of age - 5 ml (1 tsp) every 4 hours

Children under 6 years of age - Do not use

**Inactive Ingredients:**Aloe Vera, Aspartame, Honey, Menthol, Methylparaben, Potassium Sorbate, Propylene Glycol, Propylparaben, Purified Water

Each 5 mls contains: sodium 5 mg, and potassium 5 mg

Phenylketonurics: Contains Phenylalanine 2.5 mg per 5 ml (teaspoonful).

**Questions or Comments?**

**305.805.3456 Monday-Friday 9AM to 5PM EST**

**www.efficientlabs.com**

**Drug Facts**

**Active ingredient** (in each teaspoonful 5 ml) **Purpose**  
 Guaifenesin 100 mg (USP).....Expectorant

**Uses** • Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus.

**Warnings**  
 Do not exceed recommended dosage

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**Stop use and ask a doctor if** • cough persists for more than 1 week, tends to recur, or is accompanied by a fever, rash, or persistent headache. A persistent cough may be a sign 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 right away. ➡



# COUGH OUT

**ADVANCED FORMULA  
EXPECTORANT**

**GUAIFENESIN • ALCOHOL FREE**

**WITH Pure Honey and Menthol**

**Drug Facts** (Continued)

**Directions**  
 Shake well immediately before each use • do not exceed 6 doses in any 24 hour period.

Age	Dose
Adults and children 12 years and over	10 ml (2 tps) every 4 hrs.
Children 6 to under 12 years of age	5 ml (1 tsp) every 4 hrs.
Children under 6 years of age	Do not use

**Other information**  
 Each 5 mls contains: sodium 5 mg, and potassium 5 mg.  
 Phenylketonurics: Contains Phenylalanine 2.5 mg per 5 ml (teaspoonful). **Tamper Evident Feature:** Do not use if cap seal is torn, broken or missing. Store between 15°-30°C (59°-86°F).  
 Measurement cup included. Does not contain alcohol or narcotic. Product color & Flavor may vary due to natural honey.

**Inactive ingredients** Aloe Vera, Aspartame, Honey, Menthol, Methylparaben, Potassium Sorbate, Propylene Glycol, Propylparaben, Purified Water.

**Questions or Comments? 305-805-3456**  
 Monday - Friday (9 AM - 5 PM EST) or  
 www.efficientlabs.com

Other cold formulas: Mielim y Mas®, Rompe Pecho®, Rompe Pecho® DM, Rompe Pecho® SF, Rompe Pecho® CF and Rompe Pecho® SF FLU.

Distributed by  
 Efficient Laboratories, Inc., Miami, FL 33166  
 Made in U.S.A.

Lot #: \_\_\_\_\_

Exp. Date: \_\_\_\_\_ Rev 10/18

Net Wt. 6 fl. oz. (178 mls)

<b>COUGH OUT</b>			
guaifenesin liquid			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58593-255
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL	
<b>Inactive Ingredients</b>			
<b>Ingredient Name</b>	<b>Strength</b>		
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)			
<b>HONEY</b> (UNII: Y9H1V576FH)			
<b>MENTHOL</b> (UNII: L7T10EIP3A)			
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)			

<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ASPARTAME</b> (UNII: Z0H242BBR1)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58593-255-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/1997	05/16/2023
2	NDC:58593-255-06	178 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/1997	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/01/1997	

**Labeler** - Efficient Laboratories Inc. (969044932)

**Registrant** - Efficient Laboratories Inc. (969044932)

### Establishment

Name	Address	ID/FEI	Business Operations
Dextrum Laboratories Inc.		007392322	manufacture(58593-255)

Revised: 5/2023

Efficient Laboratories Inc.