

**LEADER COUGH TABS - guaifenesin tablet**  
**Cardinal Health**

*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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**Drug Facts**

**Active ingredient** (per tablet)

Guaifenesin 200mg

**Purpose**

Expectorant

**Uses**

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus
- helps make coughs more productive

**Warnings**

**Ask doctor before use if you have**

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

**Stop use and ask doctor if**

- Symptoms are accompanied by fever, rash or persistent headache
- cough persists for more than 1 week or tends to recur

**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 immediately.

**Directions**

- **Adults and children 12 years of age and over:** take 1 to 2 tablets every 4 hours as needed
- **Children 6 to 10 under 12 years of age:** take 1/2 to 1 tablet every 4 hours as needed
- **Children under 6 years of age:** consult a doctor

**Do not exceed 6 doses in a 24 hour period or as directed by a doctor**

**Other Information**

store at 15°-30°C (59°-86°F)

## Inactive ingredients

FD C red No. 40 (Al-lake), magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, silicon dioxide, sodium starch glycolate, stearic acid.

CAUTION: DO NOT USE IF IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSING

NDC 37205-466-72

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# Cough Tabs

Guaifenesin 200mg  
**Expectorant**

Relieves Chest Congestion  
Makes Coughs More Productive  
Immediate Release Tablets



60 TABLETS

**Drug Facts** (continued)

**Directions**

- Adults and children 12 years of age and over: take 1 to 2 tablets every 4 hours as needed
- Children 6 to under 12 years of age: take 1/2 to 1 tablet every 4 hours as needed
- Children under 6 years of age: consult a doctor

Do not exceed 6 doses in a 24 hour period or as directed by a doctor

**Other information** store at 15°-30° C (59°-86°)

**Inactive ingredients** FD&C red # 40 (Al-lake), magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, silicon dioxide, sodium starch glycolate, stearic acid

Distributed By: Cardinal Health  
Dublin, Ohio 43017  
www.myleader.com  
1-800-200-6313 CIN 3634318

Rev 8/09 RFLDR

All Leader® Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund.



## LEADER COUGH TABS

guaifenesin tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:37205-466
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	200 mg

### Inactive Ingredients

Ingredient Name	Strength
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POVIDONE (UNII: FZ989GH94E)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

### Product Characteristics

<b>Color</b>	red (rose)	<b>Score</b>	2 pieces
<b>Shape</b>	ROUND	<b>Size</b>	10mm

<b>Flavor</b>		<b>Imprint Code</b>	151
<b>Contains</b>			
<b>Packaging</b>			
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>
1	NDC:37205-466-72	1 in 1 BOTTLE	
<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part341	03/01/2005	

**Labeler** - Cardinal Health (097537435)

**Registrant** - Reese Pharmaceutical Co (004172052)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Reese Pharmaceutical Co		004172052	relabel(37205-466) , repack(37205-466)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Advance Pharmaceutical Inc		187824339	manufacture(37205-466)