

**TOPCARE TAB TUSSIN- guaifenesin tablet**  
**TOPCO ASSOCIATES LLC**

*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 400mg

**Purpose**

Expectorant3

**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 tablet every 4 hours as needed
- **Children 6 to 10 under 12 years of age:** take 1/2 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

magnesium stearate, maltodextrin, microcrystalline cellulose, povidone K30, povidone 90F, silicon dioxide, stearic acid.



# TOPCARE TAB TUSSIN

guaifenesin tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-420
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	2 pieces
<b>Shape</b>	OVAL	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	PH063
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-420-24	2 in 1 CARTON	05/06/2021	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

<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	02/17/2021	

**Labeler** - TOPCO ASSOCIATES LLC (006935977)

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

## Establishment

Name	Address	ID/FEI	Business Operations
Reese Pharmaceutical Co		004172052	relabel(36800-420) , repack(36800-420)

## Establishment

Name	Address	ID/FEI	Business Operations
Pharbest		557054835	manufacture(36800-420)

Revised: 5/2021

TOPCO ASSOCIATES LLC