

**SIMPEX GUAIFENESIN - guaifenesin tablet**  
**Simpex Pharma Pvt. Ltd**

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**SIMPEX Guaifenesin**

**Drug Facts**

***Active ingredient (in each tablet)***

Guaifenesin 400 mg

***Purpose***

Expectorant

***Uses***

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

***Warnings***

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

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

**Stop use and ask a doctor if**

- cough lasts more than 7 days, recurs, or is accompanied with fever, rash, or persistent headache. These could be signs of a serious condition.

**If pregnant or breast-feeding,**

ask a health care professional before use.

**Keep out of reach of children.**

In case of overdose, get medical help or contact a poison control center right away.

***Directions***

- adults & children 12 years of age and older : take a tablet every 4 hours with a full glass of water while symptoms persist. Do not exceed 6 doses in 24 hours.
- children under 12 years of age : do not use.

## Other information

- preserve in tight containers at a temperature not exceeding 30°C.

## Inactive ingredients

colloidal anhydrous silica, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, pregelatinised starch, sodium starch glycolate type A, stearic acid

## Package Labeling:

	<p><b>Drug Facts</b></p> <p><b>Active ingredient</b> (In each tablet) Guaifenesin 400 mg .....Expectorant</p> <p><b>Purpose</b></p> <p><b>Uses</b> ■ helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive to rid the bronchial passageway of bothersome mucus</p> <p><b>Warnings</b> Ask a doctor before use if you have ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema ■ cough accompanied with excessive phlegm (mucus)</p> <p><b>Stop use and ask a doctor if</b> ■ cough lasts more than 7 days, recurs, or is accompanied with fever, rash, or persistent headache. These could be signs of a serious condition.</p> <p>If pregnant or breast-feeding, ask a health care professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a poison control center right away.</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Directions</b> ■ adults &amp; children 12 years of age and older: take a tablet every 4 hours with a full glass of water while symptoms persist. Do not exceed 6 doses in 24 hours. ■ children under 12 years of age: do not use.</p> <p><b>Other information</b> ■ preserve in tight containers at a temperature not exceeding 30°C .</p> <p><b>Inactive ingredients</b> colloidal anhydrous silica, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, pregelatinised starch, sodium starch glycolate type A, stearic acid</p> <p>Manufactured by: <b>SIMPEX PHARMA PVT. LTD.</b> C-7 to C-13 &amp; C-59 to C-64, Sigaddi Growth Center, SIDCUL, Sigaddi, Kotdwar - 246149, Distt. Pauri Garhwal, <b>SIMPEX</b> Uttarakhand, India.</p>

## SIMPEX GUAIFENESIN

guaifenesin tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76457-004
<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>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

## Product Characteristics

<b>Color</b>	red (Iron oxide red, Iron oxide yellow)	<b>Score</b>	no score
<b>Shape</b>	ROUND (Biconvex)	<b>Size</b>	6mm
<b>Flavor</b>		<b>Imprint Code</b>	;
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76457-004-00	100 in 1 CARTON; Type 0: Not a Combination Product	02/09/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	02/09/2018	

**Labeler** - Simpex Pharma Pvt. Ltd (916758275)

## Establishment

Name	Address	ID/FEI	Business Operations
Simpex Pharma Pvt. Ltd		916758275	manufacture(76457-004)

Revised: 11/2023

Simpex Pharma Pvt. Ltd