

**MUCUS RELIEF ER- guaifenesin tablet, extended release**  
**Rugby Laboratories**

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**Rugby Guaifenesin Extended Release Tablets 1200 mg**

***Drug Facts***

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***Active ingredient***  
***(in each extended-release tablet)***

Guaifenesin, USP 1200 mg

***Purpose***

Expectorant

***Uses***

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

***Warnings***

**Do not use**

- for children under 12 years of age

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

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

**Stop use and ask a doctor if**

- cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache.

These could be signs of a serious illness.

**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) right away.

***Directions***

- do not crush, chew, or break extended-release tablet
- take with a full glass of water
- this product can be administered without regard for the timing of meals
- adults and children 12 years of age and over: 1 extended-release tablet every 12 hours. Do not exceed 2 extended-release tablets in 24 hours.
- children under 12 years of age: do not use

**Other information**

- store at 20-25°C (68-77°F)

**Inactive ingredients**

colloidal silicon dioxide, copovidone, FD&C blue no. 1 aluminum lake, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone (K-30), sodium starch glycolate, stearic acid

**Questions or comments?**

Call **1-877-290-4008**



<b>MUCUS RELIEF ER</b>			
guaifenesin tablet, extended release			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0536-1249
<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	1200 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C BLUE NO. 1 ALUMINUM LAKE</b> (UNII: J9EQA3S2JM)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>COPOVIDONE K25-31</b> (UNII: D9C330MD8B)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I3O)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM STARCH GLYCOLATE TYPE A</b> (UNII: H8AV0SQX4D)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	

## Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	22mm
<b>Flavor</b>		<b>Imprint Code</b>	41;1200
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1249-71	2 in 1 CARTON	04/21/2025	
1		14 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
ANDA	ANDA217780	04/21/2025	

**Labeler** - Rugby Laboratories (079246066)

**Registrant** - TIME CAP LABORATORIES, INC. (037052099)

## Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(0536-1249)

Revised: 8/2025

Rugby Laboratories