# RUGBY CHEST CONGESTION RELIEF PE- guaifenesin/phenylephrine tablet Rugby Laboratories

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 400 mg

Phenylephrine HCl 10 mg

#### **Purpose**

Guaifenesin.....Expectorant

Phenylephrine HCl.....Nasal decongestant

#### Uses

Temporarily relieves symptoms associated with a cough ,the common cold, hay fever or other upper respiratory allergies.

- helps loosen phlegm (mucus)
- clear nasal passageways
- loosens nasal congestion
- drain bronchial tubes
- shrinks swollen membranes
- clears stuffy nose
- makes coughs more productive

## **Warnings**

## Do not exceed recommended dosage

#### Do not use

■ this product if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression,

psychiatric or emotional conditions, or Parkinson's Disease), or for 2 weeks after stopping the

MAOI drug. If you are uncertain whether your prescription drug contains an MAOI, ask a health

professional.

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

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- excessive phlegm;mucus
- difficulty in urination due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking,asthma,chronic bronchitis or emphysema

#### Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occurs
- symptoms are accompanied by fever, rash, persistent headache or excessive phlegm (mucus)
- cough and congestion do not improve within 7 days or tend to recur.

These could be signs of a serious condition.

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

**Keep out of the reach of children.** In case of overdose, get medical help or contact a Poison Control Center immediately.

#### **Directions**

- adults and children 12 years and over:
- take 1 caplet every 4 hours as needed
- children 6 to under 12 years:

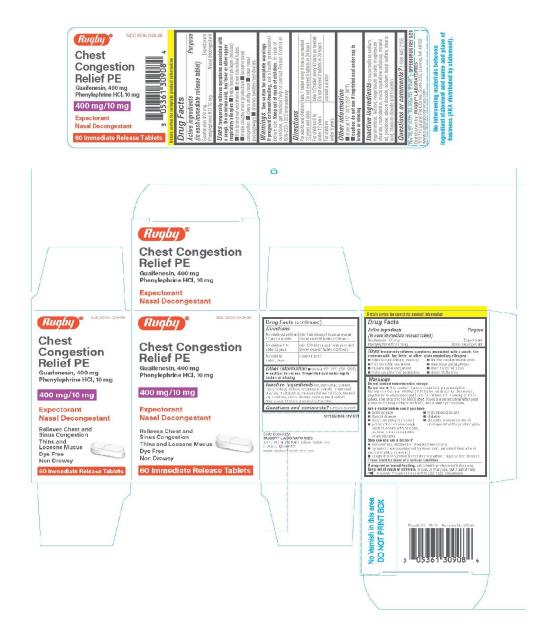
take 1/2 caplet every 4 hours as needed

■ children under 6 years: consult a doctor

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

## Inactive ingredients

lactose, magnesium silicate, croscarmellose sodium, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, mineral oil, povidone, silica, sodium lauryl sulfate, stearic acid,



# **RUGBY CHEST CONGESTION RELIEF PE**

PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -

guaifenesin/phenylephrine tablet

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (S	ource)	NDC:0536	-1309
Route of Administration	ORAL				
Active Ingredient/Active Moiety					
Ingredient Name			Basis of Str	ength	Strength
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)			Guaifenes in		400 mg

**PHENYLEPHRINE** 

10 ma

UNII:1WS297W6MV) HYDROCHLORIDE

Inactive Ingredients			
Ingredient Name	Strength		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)			
LACTOSE (UNII: J2B2A4N98G)			
MALTODEXTRIN (UNII: 7CVR7L4A2D)			
MINERAL OIL (UNII: T5L8T28FGP)			
POVIDONE (UNII: FZ989GH94E)			
MAGNESIUM SILICATE (UNII: 9B9691B2N9)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			

Product Characteristics					
Color	white	Score	2 pieces		
Shape	OVAL	Size	17mm		
Flavor		Imprint Code	PH043		
Contains					

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0536- 1309-08	1 in 1 CARTON	09/09/2020		
1		60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
2	NDC:0536- 1309-07	1 in 1 CARTON	09/09/2020		
2		30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	09/09/2020		

# Labeler - Rugby Laboratories (079246066)

# Registrant - Reese Pharmaceutical Co (004172052)

Revised: 12/2022 Rugby Laboratories