# MUCUS RELIEF SINUS- guaifenesin and phenylephrine hcl tablet, film coated Proficient Rx LP

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Major 44-542

### Active ingredients (in each immediate-release tablet)

Guaifenesin 400 mg Phenylephrine HCl 10 mg

#### **Purpose**

Expectorant Nasal decongestant

#### Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- promotes nasal and/or sinus drainage
- temporarily relieves sinus congestion and pressure

### Warnings

#### Do not use

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 do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

#### Ask a doctor before use if

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough accompanied by too much phlegm (mucus)

# When using this product

do not exceed recommended dosage.

#### Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- cough comes back or worsens
- symptoms do not improve within 7 days, come back or occur with fever, rash or persistent headache. These could be signs 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 right away.

#### **Directions**

- adults and children 12 years of age and older: take 1 tablet every 4 hours, with a full glass of water, while symptoms persist. Do not exceed 6 tablets in 24 hours.
- children under 12 years of age: do not use

#### Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

### Inactive ingredients

hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, silicon dioxide, sodium starch glycolate, stearic acid

## **Principal Display Panel**

NDC 63187-587-30

#### Mucus Relief Sinus

Guaifenesin 400 mg / Phenylephrine HCl 10 mg

Expectorant / Nasal Decongestant

- Alleviates Chest Congestion
- Relieves Nasal/Sinus Congestion
- Does Not Contain Pseudoephedrine

#### 30 Tablets

Immediate Release

# TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

50844 REV0612D54201 Distributed by **Major Pharmaceuticals** 31778 Enterprise Drive, Livonia, MI 48150 USA

Relabeled by **Proficient Rx LP** Thousand Oaks, CA 91320

Rev. 12/14 M-17 Re-order No. 006474





NDC 63187-587-30

Relabeled By: Proficient Rx LP Thousand Oaks, CA 91320



# Mucus Relief Sinus 400mg/ 10mg

#30 Tablets

Each tablet contains: Guaifenesin 400mg Expectorant / Phenylephrine HCl 10mg Nasal Decongestant

White, unscored, oval shaped tablet, with imprint code "44 542"

Product ID: RM058730

Dist. By: MAJOR® PHARMACEUTICALS 17177 N Laurel Park Drive, Suite 233 Livonia, MI 48152 USA Store at 25°C (77°F) Keep medication out of the reach of children

Mucus Relief. Sinus 400mg/ 10mg #30 Tablets Lot #:00000 SN# MASTER NDC 63187-587-30 Exp:00/00/00

Mucus Relief Sinus 400mg/ 10mg #30 Tablets Lot #:00000 SN# MASTER NDC 63187-587-30 Exp:00/00/00

Mucus Relief Sinus 400mg/ 10mg #30 Tablets Lot #:00000 SN# MASTER NDC 63187-587-30 Exp:00/00/00



GTIN: 00363187587307 SN# MASTER Exp. 00/00/00 Lot #:00000

#### **MUCUS RELIEF SINUS**

guaifenesin and phenylephrine hcl tablet, film coated

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63187-587(NDC:0904-5792)

Route of Administration ORAL

# Active Ingredient/Active Moiety Ingredient Name

Ingredient Name

GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)

PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)

Basis of Strength

400 mg

PHENYLEPHRINE HYDROCHLORIDE

10 mg

Inactive Ingredients

Ingredient Name

Strength

Ingredient Name	Strength
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

MAGNESIUM STEARATE (UNII: 70097M6I30)

MALTODEXTRIN (UNII: 7CVR7L4A2D)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)

SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)

STEARIC ACID (UNII: 4ELV7Z65AP)

Product Characteristics			
Color	WHITE	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	44;542
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63187- 587-30	1 in 1 CARTON	12/01/2015	
1		30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:63187- 587-60	1 in 1 CARTON	12/01/2015	
2		60 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 Drug	M012	04/15/2006	

# Labeler - Proficient Rx LP (079196022)

Establishment				
Name	Address	ID/FEI	Business Operations	
Proficient Rx LP		079196022	REPACK(63187-587), RELABEL(63187-587)	

Revised: 10/2023 Proficient Rx LP