# MUCUS RELIEF SINUS SEVERE CONGESTION AND PAIN- acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated HARRIS TEETER

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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#### 1167-HTE-2021-0304

#### **Drug Facts**

Active ingredients (in each caplet)	Purpose	
Acetaminophen 325 mg	Pain reliever	
Guaifenesin 200 mg	Expectorant	
Phenylephrine HCl 5 mg	Nasal decongestant	

#### Uses

- temporarily relieves:
  - nasal congestion
  - headache
  - minor aches and pains
  - sinus congestion and pressure
- promotes nasal and/or sinus drainage
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

#### **Warnings**

## Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 12 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

## Allergy alert

Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

#### Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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 you have

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

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

#### When using this product do not use more than directed

#### Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with 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.

# **Overdose warning**

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

#### **Directions**

- do not take more than directed (see Overdose warning)
- do not take more than 12 caplets in any 24-hour period
- adults and children 12 years and older: take 2 caplets every 4 hours
- children under 12 years of age: do not use

#### Other information

- store between 20-25°C (68-77°F) in a dry place
- retain outer package for complete product information

#### **Inactive ingredients**

colloidal silicon dioxide, corn starch, croscarmellose sodium, crospovidone, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

#### Questions or comments?

1-844-705-4384

#### PRINCIPAL DISPLAY PANEL

Harris Teeter™

Mucus Relief Sinus Severe Congestion & Pain

†Compare to the Active Ingredients in Mucinex® Sinus-Max® Severe Congestion & Pain Maximum Strength

Acetaminophen, Guaifenesin, Phenylephrine HCl

PAIN RELIEVER, EXPECTORANT, NASAL DECONGESTION

- Clears Sinus Congestion
- Relieves Headache
- Thins & Loosens Mucus

For Ages 12+

20 CAPLETS

**Actual Size** 



#### **MUCUS RELIEF SINUS SEVERE CONGESTION AND PAIN**

acetaminophen, quaifenesin, and phenylephrine hydrochloride tablet, coated

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:72036-167

Route of Administration ORAL

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) ACETAMINOPHEN 325 mg GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) GUAIFENESIN PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) PHENYLEPHRINE HYDROCHLORIDE 5 mg

Inactive Ingredients	
Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
CROSPOVIDONE (UNII: 2S7830E561)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics				
Color	orange	Score	no score	
Shape	OVAL	Size	19mm	
Flavor		Imprint Code	AAA;1166	
Contains				

Packaging	Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:72036- 167-02	2 in 1 CARTON	02/04/2021			
1	10 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
OTC monograph final	part341	02/04/2021	

# Labeler - HARRIS TEETER (047279351)

Revised: 3/2021 HARRIS TEETER