

**SEVERE COLD HEAD CONGESTION- acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated**

**Marc Glassman, Inc.**

*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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**1175 - MAR - 2018-1212**

***Drug Facts***

<b><i>Active ingredients (in each caplet)</i></b>	<b><i>Purpose</i></b>
Acetaminophen 325 mg	Pain reliever/fever reducer
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

**Uses**

- for the temporary relief of the following cold symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - nasal congestion
  - sinus congestion and pressure
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily reduces fever

**Warnings**

**Liver warning**

This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Sore throat warning**

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

**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.
- if you have ever had an allergic reaction to this product or any of its ingredients

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

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- 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 exceed recommended dosage**

**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 headache that lasts

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**

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)**

adults and children 12 years and over	<ul style="list-style-type: none"> <li>▪ take 2 caplets every 4 hours</li> <li>▪ swallow whole – do not crush, chew, or dissolve</li> <li>▪ do not take more than 10 caplets in 24 hours</li> </ul>
children under 12 years	<ul style="list-style-type: none"> <li>▪ ask a doctor</li> </ul>

**Other information**

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

**Inactive ingredients**

acesulfame potassium, colloidal silicon dioxide, croscarmellose sodium, crospovidone, flavor,

magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

## **PRINCIPAL DISPLAY PANEL**

68998-175-02

†Compare to the active ingredients in Tylenol® Cold Head Congestion Severe

Marc's®

Severe

Cold Head Congestion

For Adults

Pain Reliever/Fever Reducer, Nasal Decongestant, Expectorant

Acetaminophen, Phenylephrine HCl, Guaifenesin

For Relief Of:

- Headache & Fever
- Stuffy Nose & Sinus Pressure
- Chest Congestion, Clears Out Mucus

24 Cool Taste Caplets

NC

NC

NC

**Drug Facts (continued)**

**Warnings** This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. Severe liver damage may occur if you take more than 4,000 mg of acetaminophen in 24 hours. With other drugs containing acetaminophen 3 or more alcoholic drinks every day while using this product. **Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly. **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. If you have ever had an allergic reaction to this product or any of its ingredients. **Ask a doctor before use if you have** liver disease ■ diabetes ■ heart disease ■ 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).

**Drug Facts (continued)**

**Directions** ■ do not take more than directed (see overdose warning) ■ take 2 caplets every 4 hours ■ adults and children 12 years and over ■ do not take more than 10 caplets in 24 hours ■ ask a doctor if children under 12 years

**Overdose warning:** 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.

**Keep out of reach of children.** If pregnant or breast-feeding, ask a health professional before use. These could be signs of a serious condition. ■ cough comes back or occurs with rash or headache that lasts more than 7 days ■ fever gets worse or lasts more than 3 days ■ redness or swelling is present ■ new symptoms occur ■ pain, nasal congestion, or sleeplessness occur ■ nervousness, dizziness, or cough gets worse or lasts more

**Stop use and ask a doctor if** ■ When using this product do not exceed recommended dosage ■ Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

**Drug Facts**

**Active ingredients** (in each caplet) Acetaminophen 325 mg.....Pain reliever/fever reducer Guaifenesin 200 mg.....Expectorant Phenylephrine HCl 5 mg.....Nasal decongestant

**Purpose** ■ temporarily reduces fever ■ makes coughs more productive ■ helps loosen phlegm (mucus) and thin bronchial secretions to ■ nasal congestion ■ sinus congestion and pressure ■ minor aches and pains ■ headache ■ sore throat

**Uses** ■ for the temporary relief of the following cold symptoms: ■ chest congestion ■ chest congestion, clears out mucus ■ stuffy nose ■ sinus pressure ■ chest congestion, clears out mucus ■ chest congestion, clears out mucus

**Drug Facts (continued)**

Compare to the active ingredients in Tylenol® Cold Head Congestion Severe



non-drowsy  
**Severe Cold Head Congestion** For Adults

PAIN RELIEVER / FEVER REDUCER, NASAL DECONGESTANT, EXPECTORANT

Acetaminophen, Phenylephrine HCl, Guaifenesin

- For Relief of:
- Headache & Fever
  - Stuffy Nose & Sinus Pressure
  - Chest Congestion, Clears Out Mucus

24 Cool Taste Caplets



**Drug Facts (continued)**

**Other information** ■ store between 20-25°C (68-77°F) in a dry place ■ retain carton for complete product information

**Inactive ingredients** acesulfame potassium, colloidal silicon dioxide, croscarmellose sodium, crospovidone, flavor, magnesium stearate, malto-dextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

**Drug Facts (continued)**

Distributed by:  
Marc Glassman, Inc.  
West 130th Street  
Cleveland, OH 44130

FT17502MAR\_R0

†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® Cold Head Congestion Severe.

**DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN**



NDC 175-02-86899

acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68998-175
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

### Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (UNII: 2S7830E561)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>	MINT	<b>Imprint Code</b>	AAA;1119
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68998-175-02	2 in 1 CARTON	04/01/2015	
1		12 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	04/01/2015	

**Labeler** - Marc Glassman, Inc. (094487477)

Revised: 12/2018

Marc Glassman, Inc.