

# **COLD- acetaminophen, dextromethorphan hydrobromide, 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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**1138 - MAR - 2018-1211**

## **Drug Facts**

<b>Active ingredients (in each caplet)</b>	<b>Purpose</b>
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

## **Uses**

- temporarily relieves these common cold/flu symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - nasal congestion
  - cough
  - sinus congestion and pressure
- helps clear nasal passages
- promotes nasal and sinus drainage
- 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, 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)**

- 
- take 2 caplets every 4 hours

adults and children 12 years and over	<ul style="list-style-type: none"><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, corn starch, croscarmellose sodium, crospovidone, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

### **PRINCIPAL DISPLAY PANEL**

See New Warnings Information & Directions

†Compare to the active ingredients in Tylenol® Cold Multi-Symptom Daytime

Marc's®

Daytime, Non-drowsy

Cold Multi-Symptom

For Adults

Pain Reliever/Fever Reducer, Nasal Decongestant, Cough Suppressant

Acetaminophen, Phenylephrine HCl, Dextromethorphan HBr

For Relief Of:

- Headache, Fever & Sore Throat
- Nasal Congestion
- Cough

24 Cool Taste Caplets

NC

NC

NC

**Drug Facts (continued)**

**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  
 Some 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, or emphysema

**Drug Facts (continued)**

**Directions**  
 ■ do not take more than directed (see overdose warning)  
 ■ take 2 caplets every 4 hours  
 ■ do not take more than 10 caplets in 24 hours  
 ■ ask a doctor  
 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  
 ■ redness or swelling is present  
 ■ new symptoms occur  
 ■ fever gets worse or lasts more than 3 days  
 ■ pain, nasal congestion, or cough gets worse or lasts more than 7 days  
 ■ nervousness, dizziness, or sleeplessness occur  
 ■ Stop use and ask a doctor if

**When using this product do not exceed recommended dosage**  
 ■ thinking drug warfarin  
 ■ cough that occurs with too much phlegm (mucus)  
 ■ Ask a doctor or pharmacist before use if you are taking the blood

**Drug Facts**  
**Active ingredients (in each caplet) Purpose**  
 Acetaminophen 325 mg Pain reliever/fever reducer  
 Dextromethorphan HBr 10 mg Cough suppressant  
 Phenylephrine HCl 5 mg Nasal decongestant

**Drug Facts (continued)**  
**Uses** ■ temporarily relieves these common cold/flu symptoms:  
 ■ minor aches and pains ■ headache ■ sore throat  
 ■ nasal congestion ■ cough  
 ■ sinus congestion and pressure  
 ■ helps clear nasal passages  
 ■ temporarily reduces fever

See New Warnings Information & Directions

Compare to the active ingredients in Tylenol® Cold Multi-Symptom Daytime

**Marc's**

**Cold** daytime non-drowsy   
**Multi-Symptom** For Adults

PAIN RELIEVER/FEVER REDUCER, NASAL DECONGESTANT, COUGH SUPPRESSANT

**Acetaminophen, Phenylephrine HCl, Dextromethorphan HBr**

For Relief of:

- Headache, Fever & Sore Throat
- Nasal Congestion
- Cough

**24 Cool Taste Caplets** 

**Drug Facts (continued)**

**Other information**  
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**Drug Facts (continued)**

**Inactive ingredients**  
 acetaminophen, colloidal silicon dioxide, corn starch, croscarmellose sodium, crospovidone, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

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

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†This product is not manufactured or distributed by McKel Consumer Healthcare, distributor of Tylenol® Cold Multi-Symptom Daytime.

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

# COLD

acetaminophen, dextromethorphan hydrobromide, and phenylephrine hydrochloride tablet, coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68998-138
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

## Inactive Ingredients

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

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	17mm
<b>Flavor</b>	MINT	<b>Imprint Code</b>	AAA;1138
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68998-138-05	2 in 1 CARTON	02/01/2010	06/30/2024
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	02/01/2010	06/30/2024

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

Revised: 12/2022

Marc Glassman, Inc.