

**COLD MAX- acetaminophen, dextromethorphan hydrobromide, and phenylephrine hydrochloride tablet, coated**  
**Harmon Stores 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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**HAR - 1138 - 2019-1009**

**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

**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.

### **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)**

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

### PRINCIPAL DISPLAY PANEL

#### CORE VALUES

Compare to the active ingredients in Tylenol® Cold Max

Cold Max

for Adults

Acetaminophen, , Dextromethorphan HBr, Phenylephrine HCl

Pain Reliever / Fever Reducer, Cough Suppressant, Nasal Decongestant

Actual Size

For relief of:

Head + Body Aches, Cough

Fever + Sore Throat, Nasal Congestion

DAYTIME NON-DROWSY

24 CAPLETS

“Cool Taste”

CORE VALUES™

Compare to active ingredients  
in Tylenol® Cold Max\*

# Cold Max for Adults

Acetaminophen, Dextromethorphan HBr, Phenylephrine HCl  
Pain Reliever / Fever Reducer, Cough Suppressant, Nasal Decongestant

For relief of:

- Head + Body Aches
- Cough
- Fever + Sore Throat
- Nasal Congestion



24 CAPLETS

"Cool Taste"

## 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

### 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  
■ 5 or more alcoholic drinks every day 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.  
**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 non-prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.  
■ 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 ■ diabetes ■ trouble urinating due to an enlarged prostate gland

**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** acetaminophen, dextromethorphan, phenylephrine, hydrocodone, croscarmellose sodium, crospovidone, colloidal silicon dioxide

**Drug Facts (continued)**  
■ 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  
■ 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**  
■ **adults and children 12 years and over**  
■ take 2 caplets every 4 hours  
■ swallow whole – do not crush, chew, or dissolve  
■ do not take more than 10 caplets in 24 hours  
■ ask a doctor  
**12 years and under**  
■ ask a doctor

**Drug Facts (continued)**  
magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide



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\*This product is not manufactured or distributed by McKel Consumer Healthcare, distributor of Tylenol® Cold Max.

DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN

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COLD MAX

acetaminophen, dextromethorphan hydrobromide, and phenylephrine hydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63940-332
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 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)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (UNII: 2S7830E561)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	white	Score	no score
Shape	OVAL	Size	17mm
Flavor	MINT	Imprint Code	AAA;1138
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63940-332-05	2 in 1 CARTON	09/11/2018	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	09/11/2018	06/30/2024

**Labeler** - Harmon Stores Inc. (804085293)

Revised: 8/2022

Harmon Stores Inc.