# COLD RELIEF MULTI-SYMPTOM DAYTIME- acetaminophen, dextromethorphan hydrobromide, and phenylephrine hydrochloride tablet, coated Meijer

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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#### MEI-1138-2022-0923

### **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		

#### 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

Overdose warning

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.

# In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Ouick 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> <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	ask a doctor

#### 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

#### Questions or comments?

1-844-705-4384

# PRINCIPAL DISPLAY PANEL

NDC 41250-138-05

Compare to Tylenol® Cold Max active ingredients†

Meijer®

Cold Max

Acetaminophen | Dextromethorphan HBr, Phenylephrine HCl

Pain Reliever/Fever Reducer, Cough Suppressant, Nasal Decongestant

Relief of:

- Head & Body Aches
- Fever & Sore Throat
- Cough

Nasal Congestion

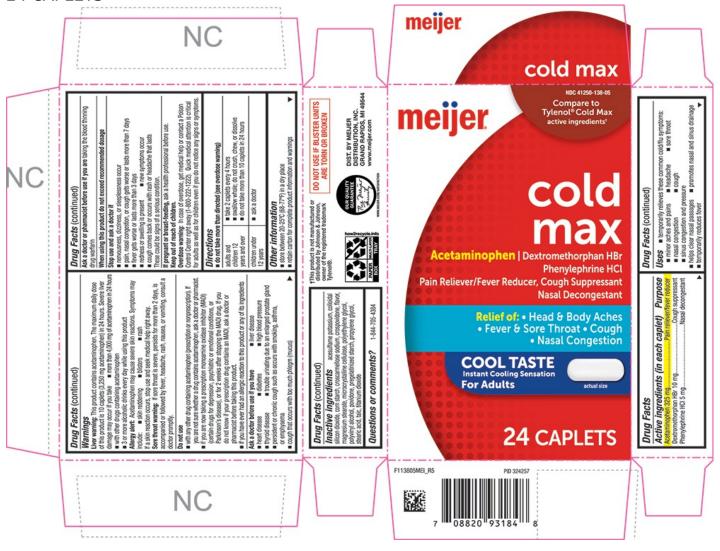
Cool Taste

**Instant Cooling Sensation** 

For Adults

actual size

24 CAPLETS



## **COLD RELIEF MULTI-SYMPTOM DAYTIME**

acetaminophen, dextromethorphan hydrobromide, and phenylephrine hydrochloride tablet, coated

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:4125	50-138	
Route of Administration	ORAL				
Active Ingredient/Active Moiety					
Ingre	Basis of St	renath	Strength		

325 mg

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) | ACETAMINOPHEN

<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			
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)				
CROSPOVIDONE (UNII: 2S7830E561)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POLYVINYL ALCOHOL (UNII: 532B59J990)				
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)				
STARCH, PREGELATINIZED CORN (UNII: 08232NY3SJ)				
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			
NDC:41250- 138-05	2 in 1 CARTON	11/07/2014				
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	11/07/2014	

# **Labeler -** Meijer (006959555)

Revised: 9/2022 Meijer