

**COLD MAX- acetaminophen, dextromethorphan hydrobromide, and phenylephrine hydrochloride tablet, coated**  
**DISCOUNT DRUG MART**

*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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**DDM-1138-2022-0803**

**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 and warnings

### 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

### Questions or comments?

1-844-705-4384

### PRINCIPAL DISPLAY PANEL

DISCOUNT drg mart FOOD MARKET

NDC 53943-138-05

†Compare to the active ingredients in Tylenol® Cold Max

FOR ADULTS

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
- 24 COOL TASTE CAPLETS
- Actual Size



# COLD MAX

acetaminophen, dextromethorphan hydrobromide, and phenylephrine hydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53943-138
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name		Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)		10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 04JA59TNSJ)		5 mg

UNII:1WS297W6MV)		HYDROCHLORIDE	5 mg	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)				
CROSPVIDONE (UNII: 2S7830E561)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POLYVINYL ALCOHOL (UNII: 532B59J990)				
POVIDONE (UNII: FZ989GH94E)				
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
<b>Product Characteristics</b>				
<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>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:53943-138-05	2 in 1 CARTON	11/13/2009	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph final	part341	11/13/2009		

**Labeler -** DISCOUNT DRUG MART (047741335)