

**COLD RELIEF MULTI-SYMPTOM- acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, and phenylephrine hydrochloride**

**TopCare**

*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.*

-----

**1150 - TCR - 2018-1227**

**COLD MAX DAY**

***Drug Facts***

---

<b><i>Active ingredients (in each day caplet)</i></b>	<b><i>Purpose</i></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

**COLD MAX NIGHT**

***Drug Facts***

---

<b><i>Active ingredients (in each night caplet)</i></b>	<b><i>Purpose</i></b>
Acetaminophen 325 mg	Pain reliever/fever reducer
Chlorpheniramine maleate 2 mg	Antihistamine
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
  - runny nose and sneezing

- cough
- sinus congestion and pressure
- helps clear nasal passages
- relieves cough to help you sleep
- temporarily reduces fever

## **Warnings**

### **Liver warning**

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 12 caplets in 24 hours, which is the maximum daily amount
- 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
- thyroid disease
- high blood pressure
- diabetes
- glaucoma
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- a breathing problem such as emphysema or chronic bronchitis

### **Ask a doctor or pharmacist before use if you are**

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

## When using this product

- do not exceed recommended dosage

## In addition, when using Cold Multi-Symptom Night:

- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

## 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)
- do not take Day and Night caplets at the same time
- do not take more than a total of 12 caplets in 24 hours

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></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

### Cold Multi-Symptom Day

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

## **Cold Multi-Symptom Night**

acesulfame potassium, colloidal silicon dioxide, croscarmellose sodium, FD&C blue #1 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

### **PRINCIPAL DISPLAY PANEL**

TopCare® Health

36800-250-56

Cold Max

Day + Night

For Adults

Our Pharmacists Recommend

Daytime Non-Drowsy

Pain Reliever/Fever Reducer - Acetaminophen

Cough Suppressant – Dextromethorphan HBr

Nasal Decongestant - Phenylephrine HCl

Day Caplet Relieves:

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

12 Cool Taste Caplets

Nighttime

Pain Reliever/Fever Reducer - Acetaminophen

Nasal Decongestant - Phenylephrine HCl

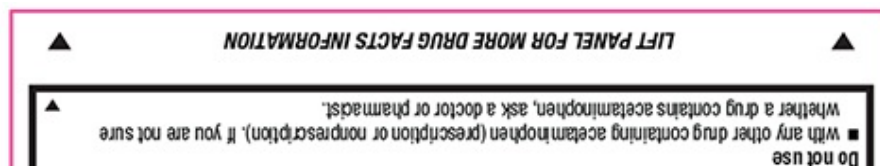
Antihistamine – Chlorpheniramine Maleate\*

Night Caplet Relieves:

- Head + Body Aches
- Fever + Sore Throat
- Cough
- Nasal Congestion
- Runny Nose\*

\*Antihistamine in Nighttime Only

8 Cool Taste Caplets



<p><b>Warnings:</b> 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</p> <p><b>Alert:</b> Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin redness ■ blisters ■ rash</p> <p><b>Sore throat warning:</b> 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.</p>	<p><b>Warnings:</b> 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</p> <p><b>Alert:</b> Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin redness ■ blisters ■ rash</p> <p><b>Sore throat warning:</b> 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.</p>
<p><b>Uses</b></p> <p>temporarily relieves these common cold/flu symptoms: ■ minor aches and pains ■ headache ■ sore throat ■ nasal congestion ■ runny nose and sneezing ■ cough ■ sinus congestion and pressure ■ helps clear nasal passages ■ relieves cough to help you sleep ■ temporarily reduces fever</p>	<p><b>Uses</b></p> <p>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</p>
<p><b>Drug Facts</b></p> <p><b>Active ingredients (in each night caplet)</b></p> <p>Acetaminophen 325 mg... Pain reliever/fever reducer  Chlorpheniramine maleate 2 mg... Antihistamine  Dextromethorphan HBr 10 mg... Cough suppressant  Phenylephrine HCl 5 mg... Nasal decongestant</p> <p><b>Purpose</b></p>	<p><b>Drug Facts</b></p> <p><b>Active ingredients (in each day caplet)</b></p> <p>Acetaminophen 325 mg... Pain reliever/fever reducer  Dextromethorphan HBr 10 mg... Cough suppressant  Phenylephrine HCl 5 mg... Nasal decongestant</p> <p><b>Purpose</b></p>

**DO NOT TAKE THE DAY AND NIGHT CAPLETS AT THE SAME TIME.** Do not take more than a total of 10 caplets in a 24-hour period. Take only as directed.



For Adults

# Cold Max Day + Night



NDC 36800-250-56

For Adults

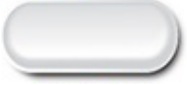
# Cold Max Day + Night



**DAYTIME**  
**NON-DROWSY**  
PAIN RELIEVER/FEVER REDUCER - **ACETAMINOPHEN**  
COUGH SUPPRESSANT - DEXTROMETHORPHAN HBr  
NASAL DECONGESTANT - PHENYLEPHRINE HCl

**DAY CAPLET RELIEVES:**

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



**NIGHTTIME**  
PAIN RELIEVER/FEVER REDUCER - **ACETAMINOPHEN**  
COUGH SUPPRESSANT - DEXTROMETHORPHAN HBr  
NASAL DECONGESTANT - PHENYLEPHRINE HCl  
ANTIHISTAMINE\* - CHLORPHENIRAMINE MALEATE\*

**NIGHT CAPLET RELIEVES:**

- Head + Body Aches
- Fever + Sore Throat
- Cough
- Nasal Congestion
- Runny Nose\*

\*Antihistamine in



NC

NC

actual size

Nighttime Only

actual size

12 COOL TASTE CAPLETS

8 COOL TASTE CAPLETS

**Drug Facts (continued)**

**Inactive ingredients**  
 Cold Max Day: 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

**Cold Max Night**: acesulfame potassium, colloidal silicon dioxide, croscarmellose sodium, FD&C blue #1 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

**Drug Facts (continued)**

■ 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 ■ thyroid disease ■ high blood pressure ■ diabetes ■ glaucoma
- trouble urinating due to an enlarged prostate gland ■ cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- a breathing problem such as emphysema or chronic bronchitis

**Ask a doctor or pharmacist before use if you are**

- taking the blood thinning drug warfarin ■ taking sedatives or tranquilizers

**When using this product** ■ do not exceed recommended dosage

**In addition, when using Cold Max Night**

- excitability may occur, especially in children
- marked drowsiness may occur ■ alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks

**Stop use and ask a doctor if** ■ nervousness, dizziness, or sleepiness 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

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)

- do not take Day and Night caplets at the same time
- do not take more than a total of 10 caplets in 24 hours
- take 2 caplets every 4 hours
- swallow whole – do not crush, chew, or dissolve

adults and children

- ask a doctor

children under 12 years

**Other information**

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

DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN

DISTRIBUTED BY TOPCO ASSOCIATES LLC  
 ELK GROVE VILLAGE, IL 60007 © TOPCO AAPA0318  
 QUESTIONS? 1-888-423-0139  
 topcare@topco.com  
 www.topcarebrand.com



This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.



F115002TCR\_R2

NC

COLD RELIEF MULTI-SYMPTOM			
acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, and phenylephrine hydrochloride kit			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-250

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-250-56	1 in 1 CARTON	10/01/2011	

**Quantity of Parts**

Part #	Package Quantity	Total Product Quantity
Part 1	1 BLISTER PACK	12
Part 2	1 BLISTER PACK	8

**Part 1 of 2****ACETAMINOPHEN, DEXTROMETHORPHAN HYDROBROMIDE,  
PHENYLEPHRINE HYDROCHLORIDE**

acetaminophen, dextromethorphan hydrobromide, and phenylephrine hydrochloride tablet, coated

**Product Information**

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: 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)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL (capsule-shaped)	<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		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		

## Part 2 of 2

### ACETAMINOPHEN, CHLORPHENIRAMINE MALEATE, DEXTROMETHORPHAN HYDROBROMIDE, PHENYLEPHRINE HYDROCHLORIDE

acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, and phenylephrine hydrochloride tablet, coated

## Product Information

<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
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 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)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	



<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>ALUMINUM OXIDE</b> (UNII: LM26O6933)	
<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, PREGELATINIZED 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>	blue	<b>Score</b>	no score
<b>Shape</b>	OVAL (capsule-shaped)	<b>Size</b>	17mm
<b>Flavor</b>	MINT	<b>Imprint Code</b>	AAA;1139
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 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		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/01/2011	

### Labeler - TopCare (006935977)