

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 - 2022-1208

COLD MAX DAY

Drug Facts

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

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

- take 2 caplets every 4 hours
- swallow whole – do not crush,

12 years and over	chew, or dissolve
children under 12 years	<ul style="list-style-type: none"> 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

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

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

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.

MAX DAY
COLD NIGHT

Day Facts	Night Facts
<p>Drug Facts</p> <p>Active ingredients (in each Day caplet) Acetaminophen 325 mg...Pain reliever/fever reducer Dextromethorphan HBr 10 mg.....Cough suppressant Phenylephrine HCl 5 mg.....Nasal decongestant</p>	<p>Drug Facts</p> <p>Active ingredients (in each Night caplet) 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>Uses</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>Uses</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>Warnings</p> <p>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</p> <p>Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash</p> <p>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.</p> <p>Do not use</p> <p>■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</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.

MAX DAY
COLD NIGHT

For Adults

Cold Max Day + Night



NDC 36800-250-56

For Adults

Cold Max Day + Night



DAYTIME
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



actual size



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*



actual size

*Antihistamine in Nighttime Only

12 COOL TASTE CAPLETS

8 COOL TASTE CAPLETS

Drug Facts (continued)

Inactive ingredients
Cold Max Day: 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.
Cold Max Night: 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.

Other information

■ store between 20-25°C (68-77°F) in a dry place

■ retain carton for complete product information and warnings

children under 12 years ■ ask a doctor

adults and children ■ take 2 caplets every 4 hours

■ do not take more than a total of 10 caplets in 24 hours

■ do not take Day and Night caplets at the same time

■ do not take more than directed (see overdose warning)

any signs or symptoms.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away.

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.

■ 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

■ redness or swelling is present

■ cough comes back or occurs with rash or headache that lasts

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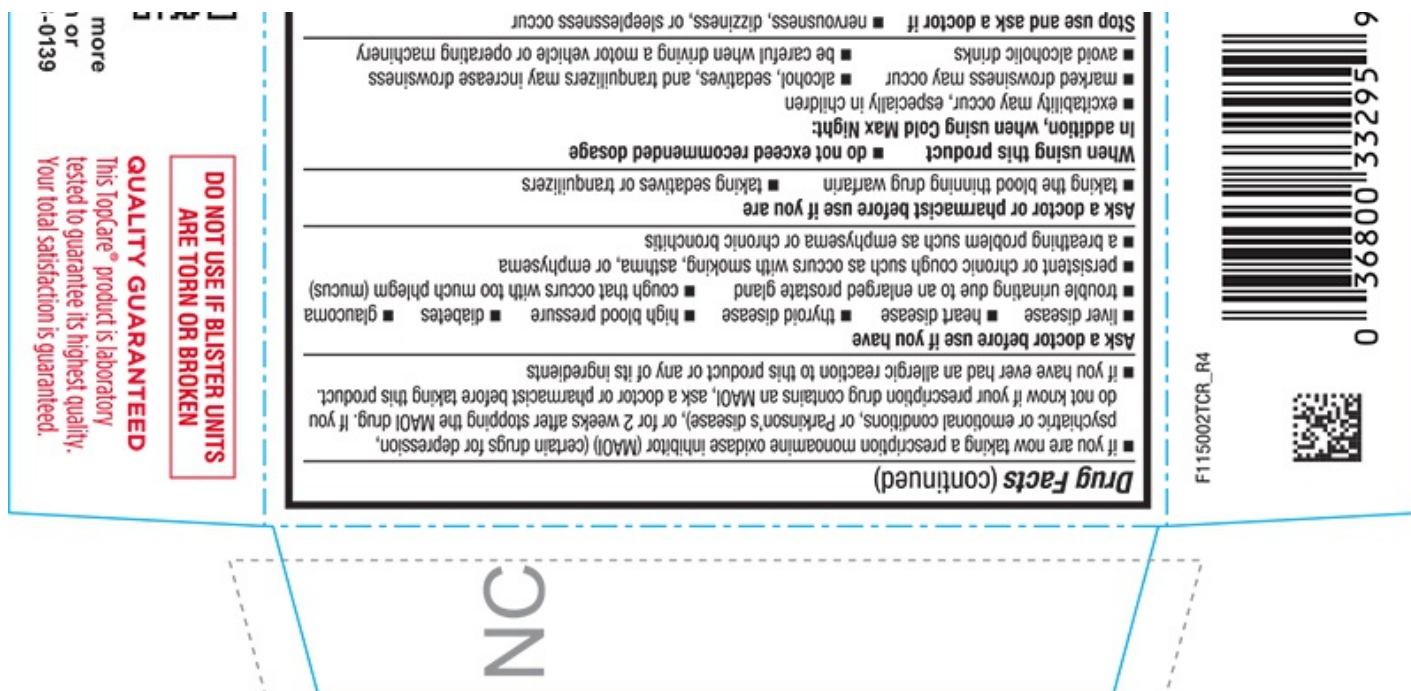
QUESTIONS? 1-888-423-0139

topcare@topco.com

www.topcarebrand.com



Scan here for information
call 1-888-423



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
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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				
Color	white	Score	no score	
Shape	OVAL (capsule-shaped)	Size	17mm	
Flavor	MINT	Imprint Code	AAA;1138	
Contains				
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	
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name		Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		325 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)		2 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)		10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)		5 mg

Inactive Ingredients	
Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
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			
Color	blue	Score	no score
Shape	OVAL (capsule-shaped)	Size	17mm
Flavor	MINT	Imprint Code	AAA;1139
Contains			

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)

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TopCare