

**COLD MULTI SYMPTOM DAYTIME NIGHTTIME- acetaminophen,
chlorpheniramine maleate, dextromethorphan hydrobromide, and
phenylephrine hydrochloride
Chain Drug Marketing Association**

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.

QCH - 1150 - 2019-1007

COLD MAX DAY

Drug Facts

<i>Active ingredients (in each 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 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. 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)
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

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
- 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 10 caplets in 24 hours
-

adults and children 12 years and over	<ul style="list-style-type: none">▪ take 2 caplets every 4 hours▪ swallow whole – do not crush, 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 and warnings

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

PRINCIPAL DISPLAY PANEL

NDC 63868-015-20

QUALITY CHOICE

Daytime & Nighttime

Cold Max Multi-Symptom

Acetaminophen, Dextromethorphan HBr, Phenylephrine HCl, Chlorpheniramine Maleate*

Pain Reliever/Fever Reducer, Cough Suppressant, Nasal Decongestant, Antihistamine*

Relief of:

Head & Body Aches

Fever & Sore Throat

Cough

Nasal Congestion

Runny Nose*

*Antihistamine in Nighttime Only

actual size

12 Day/8 Night Caplets

20 COOL TASTE CAPLETS

LIFT PANEL FOR MORE DRUG FACTS INFORMATION

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 redness ■ 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.	
Drug Facts 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	Drug Facts 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
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	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

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.

COLD
MAX
DAY



Daytime & Nighttime
**Cold Max
Multi-Symptom**



NDC 63868-015-20

Daytime & Nighttime
**Cold Max
Multi-Symptom**

Acetaminophen, Dextromethorphan HBr,

Phenylephrine HCl, Chlorpheniramine Maleate*

**Pain Reliever | Fever Reducer, Cough Suppressant,
Nasal Decongestant, Antihistamine***

Relief of:
Head & Body Aches
Fever & Sore Throat
Cough
Nasal Congestion
Runny Nose*

*Antihistamine in Nighttime Only

For Adults



actual
size

12 Day/8 Night
Caplets

NC

NC

20 COOL TASTE CAPLETS

Drug Facts (continued)

Cold Max Day acetaminophen, aspirin, dextromethorphan HBr, pseudoephedrine HCl, pyrilone, phenylephrine HCl, chlorpheniramine maleate, FD&C blue #1, titanium dioxide, croscarmellose sodium, crospovidone, pregelatinized starch, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

Cold Max Night acetaminophen, aspirin, dextromethorphan HBr, pseudoephedrine HCl, pyrilone, phenylephrine HCl, chlorpheniramine maleate, FD&C blue #1, titanium dioxide, croscarmellose sodium, crospovidone, pregelatinized starch, 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

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

adults and children ■ take 2 caplets every 4 hours ■ swallow whole – do not crush, chew, or dissolve ■ ask a doctor

children under 12 years ■ ask a doctor

Warnings ■ 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.

Stop use and ask a doctor if ■ new symptoms occur ■ fever gets worse or lasts more than 3 days ■ cough comes back or occurs with rash or headache that lasts ■ persistent or chronic cough such as occurs with smoking, asthma, or emphysema ■ trouble urinating due to an enlarged prostate gland ■ liver disease ■ heart disease ■ thyroid disease ■ high blood pressure ■ diabetes ■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis

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 ■ be careful when driving a motor vehicle or operating machinery

Ask a doctor or pharmacist before use if you are ■ taking the blood thinning drug warfarin ■ taking sedatives or tranquilizers ■ taking a prescription drug that 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

Drug Facts (continued) ■ if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychotic, 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

**DO NOT USE IF BUSTER UNITS
ARE TORN OR BROKEN**



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FT150020CH_R1



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COLD MULTI SYMPTOM DAYTIME NIGHTTIME

acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, and phenylephrine hydrochloride kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-015
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-015-20	1 in 1 CARTON	03/06/2013	

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
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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)	

CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CROSPROVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
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 (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
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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)	
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, 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	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	03/06/2013	

Labeler - Chain Drug Marketing Association (011920774)

Revised: 12/2022

Chain Drug Marketing Association