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

QCH - 1150 - 2019-1007

COLD MAX DAY

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

COLD MAX NIGHT

Drug Facts

Active ingredients (in each caplet)	Purpose
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

- take 2 caplets every 4 hours
- swallow whole do not crush, chew, or dissolve

over	
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 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

OUALITY 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

LIFT PANEL FOR MORE DRUG FACTS INFORMATION whether a drug contains acetaminophen, ask a doctor or pharmadist. with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure tever, headache, rash, nausea, or vomiting, consult a doctor promptly. Sore throat waming: If sore throat is severe, persists for more than 2 days, is accompanied or followed by If a skin reaction occurs, stop use and seek medical help right away. m skin reddening m blisters m rash Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: 3 or more alcoholic drinks every day while using this product with other drugs containing acetaminophen ■ more than 4,000 mg of acetaminophen in 24 hours (3,250 mg acetaminophen) in 24 hours. Severe liver damage may occur if you take FINER WARNING: This product contains acetaminopher. The maximum daily dose of this product is 10 caplets Marnings femboranly reduces fever temporarily reduces fever telieves cough to help you steep bromotes nasal and sinus drainage µejbe cjest usesj basesôes pelbs cjest usssj bssades a sinus congestion and pressure siuns coudestion and bressure ■ Lunny nose and sneezing u6nco ■ u6nco ■ ■ usasi congestion ■ sore throat ■ usesi congestion ■ sore throat иевательный ■ winor aches and pains minor sches and pains meadache symptoms: s) wbrows: temporarily relieves these common cold/flu femborarily relieves these common cold/flu səsn səsn Dextromethorphan HBr 10 mg.....Cough suppressant Phenylephrine HCl 5 mg...... Masal decongestant Chlorpheniramine maleate 2 mg.....Antihistamine Dextromethorphan HBr 10 mg.....Cough suppressant Acetaminophen 325 mg...Pain reliever/fever reducer (in each night caplet) (in each day caplet) Active ingredients Active ingredients Purpose Purpose Drug Facts Drug Facts NICHT COLD WAX YAO Do not take more than a total of 10 caplets in a 24-hour period. Take only as directed. COLD DO NOT TAKE THE DAY AND NIGHT CAPLETS AT THE SAME TIME.



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



20 COOL TASTE CAPLETS

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Drug Facts (continued)

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

■ SSK & doctor	children under 12 years
 ■ take 2 caplets every 4 hour ■ swallow whole - do not or 	adults and children 12 years and over

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These could be signs of a serious condition.

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Orug Facts (continued)





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

Packaging

l	# 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

4				
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

Active ingredient/Active Ploiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1W5297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients

Ingredient Name	Strength	
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)		
CROSPOVIDONE, 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 Drug	M012			

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	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D)	ACETAMINOPHEN	325 mg		

CHLORPHENIRAMINE MALEATE (UNII: V1Q0090J9Z) (CHLORPHENIRAMINE - UNII: 3U6I01965U)	CHLORPHENIRAMINE MALEATE	2 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS 297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
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 Drug	M012			

Marketing Information				
Marketing	Application Number or Monograph	Marketing Start	Marketing End	
Category	Citation	Date	Date	

OTC Monograph Drug	M012	03/06/2013	

Labeler - Chain Drug Marketing Association (011920774)

Revised: 12/2024 Chain Drug Marketing Association