

COLD MULTI-SYMPTOM- acetaminophen, dextromethorphan hbr, phenylephrine hcl tablet, film coated

ARMY AND AIR FORCE EXCHANGE SERVICE

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.

Exchange Select 44-470C-CMS

Active ingredients (in each caplet)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
 - minor aches and pains
 - nasal congestion
 - headache
 - cough
 - sinus congestion and pressure
 - sore throat
- helps clear nasal passages
- promotes nasal and sinus drainage
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. 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:

- blisters
- rash
- skin reddening

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 using 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

- diabetes
- cough that occurs with too much phlegm (mucus)
- difficulty in urination due to enlargement of the prostate gland
- liver disease
- heart disease
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- thyroid disease
- high blood pressure

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
- new symptoms occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- 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.

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt 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**
- adults and children 12 years and over
 - take 2 caplets every 4 hours
 - swallow whole - do not crush, chew, or dissolve
 - do not take more than 10 caplets in 24 hours
- children under 12 years: ask a doctor

Other information

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°)
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, croscarmellose sodium, crospovidone, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, stearic acid, sucralose, talc, titanium dioxide

Questions or comments?

1-800-426-9391

Principal Display Panel

exchange[®]select[™]

Compare To The Active Ingredients of Tylenol[®] COLD MAX*

Pseudoephedrine Free

**COLD
MULTI-SYMPTOM**

Acetaminophen,

Dextromethorphan HBr, Phenylephrine HCl

Pain reliever/Fever reducer, Cough suppressant &
Nasal decongestant

Relieves:

- Headache
- Fever
- Sore Throat
- Coughing
- Nasal Congestion

Actual Size

24 Caplets

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Tylenol[®] COLD MAX.

"SATISFACTION GUARANTEED OR YOUR MONEY BACK"

Manufactured For Your Military Exchanges

Distributed by: LNK International, Inc.

Hauppauge, NY 11788

1-800-426-9391

50844 REV0718A47008

Drug Facts
 KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION
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 (in each caplet)
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 Dextromethorphan HBr 10 mg... Cough suppressant
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 ■ minor aches and pains
 ■ nasal congestion
 ■ headache
 ■ cough
 ■ sinus congestion and pressure
 ■ sore throat
 ■ helps clear nasal passages

exchange **select**

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 Tylenol® COLD MAX®
 Pseudoephedrine Free

COLD

MULTI-SYMPTOM

Acetaminophen,
 Dextromethorphan HBr, Phenylephrine HCl
 Pain reliever/Fever reducer, Cough suppressant &
 Nasal decongestant

- Relieves:**
- Headache
 - Fever
 - Sore Throat
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Actual Size

24 Caplets

quality
value

No print area
 Lot no. & Exp. Date

50844 REV0718A47008

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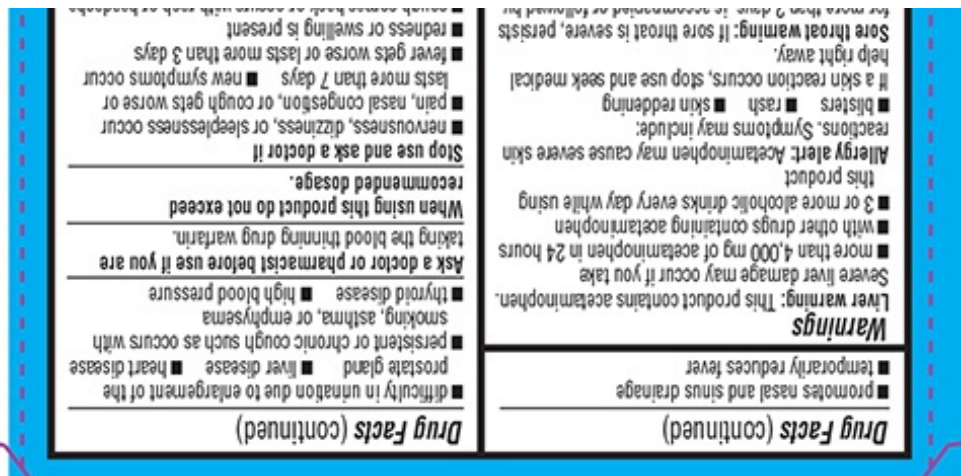
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 ■ Ask a doctor before use if you have ■ diabetes ■ cough that occurs with too much phlegm (mucus)
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 ■ Cough comes back or occurs with rash or meagane that lasts. These could be signs of a serious condition.
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B-0066E-470C08MSR
 REV0718A47008



44-470

COLD MULTI-SYMP TOM

acetaminophen, dextromethorphan hbr, phenylephrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:5530 1-470
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:36 2O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS29 7W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (UNII: 2S7830E561)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics				
Color	WHITE	Score	no score	
Shape	OVAL	Size	17mm	
Flavor		Imprint Code	44;470	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55301-470-08	2 in 1 CARTON	07/15/2005	
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		07/15/2005	

Labeler - ARMY AND AIR FORCE EXCHANGE SERVICE (001695568)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(55301-470)