

COLD MULTI-SYMPATOM NON-DROWSY, DAYTIME- acetaminophen, dextromethorphan hbr, phenylephrine hcl tablet
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 44-560

Active ingredients (in each gelcap)

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/flu symptoms:
 - minor aches and pains
 - headache
 - nasal congestion
 - cough
 - sore throat
 - sinus congestion and pressure
- 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 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
- diabetes
- heart disease
- high blood pressure
- thyroid disease
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough that occurs with too much phlegm (mucus)

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
- persistent cough lasts for more than one week, tends to recur, or is accompanied by fever, rash, or persistent headache

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 gelcaps every 4 hours
 - do not take more than 10 gelcaps 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°F)
- avoid high humidity
- see end flap for expiration date and lot number

Inactive ingredients

croscarmellose sodium, crospovidone, D&C red #28, FD&C blue #1, FD&C red #40, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, shellac glaze, silica gel, stearic acid, titanium dioxide

Questions or comments?

1-800-426-9391

Principal Display Panel

exchange **select™**

Compare To The Active Ingredients of
Tylenol® COLD MAX Day*

Pseudoephedrine Free

***COLD
MULTI-SYMPTOM***

***NON-DROWSY
DAYTIME***

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

Relieves: • *Sore Throat*
• *Headache* • *Coughing*
• *Fever* • *Nasal Congestion*

Rapid Release

Actual Size

24 Gelcaps

**quality
value**

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

"SATISFACTION GUARANTEED OR YOUR MONEY BACK"

Manufactured For Your Military Exchanges
Distributed by: LNK International, Inc., Hauppauge, NY 11788
1-800-426-9391

*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Tylenol® COLD MAX Day.

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exchange **select**™

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Pseudoephedrine Free

COLD MULTI-SYMPTOM

NON-DROWSY DAYTIME

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- Fever

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Drug Facts (continued)

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Drug Facts (continued)

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Drug Facts (continued)

Uses ■ temporarily relieves these common cold and flu symptoms: ■ headache ■ cough ■ sinus congestion and pressure ■ nasal congestion ■ sore throat ■ minor aches and pains ■ helps clear nasal passages

Drug Facts (continued)

Directions

■ 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
- diabetes
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Drug Facts (continued)

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Drug Facts (continued)

propylene glycol, shellac glaze, silica gel, stearic acid, titanium dioxide

Questions or comments? 1-800-426-9391

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 REV0216C56008

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Drug Facts (continued)

- temporarily nasal and sinus drainage
- promotes nasal and sinus drainage

Warnings

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 - more than 4,000 mg in 24 hours, which is the maximum daily amount
 - with other drugs containing acetaminophen
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- If a skin reaction occurs, stop use and seek medical help right away.
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- 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 (continued)

- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- high blood pressure
- thyroid disease
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Keep out of reach of children. In case of accidental overdose, call for medical help or contact a Poison

Exchange Select 44-560

COLD MULTI-SYMP TOM NON-DROWSY, DAYTIME

acetaminophen, dextromethorphan hbr, phenylephrine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55301-560
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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CROSPVIDONE (UNII: 2S7830E561)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	

Product Characteristics

Color	PURPLE, RED	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	L;0
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55301-560-08	2 in 1 CARTON	03/29/2008	
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	03/29/2008	

Labeler - ARMY AND AIR FORCE EXCHANGE SERVICE (001695568)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(55301-560)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(55301-560)