

**COLD AND FLU SEVERE, DAY AND NIGHTTIME- acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, guaifenesin, phenylephrine hcl  
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.*

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**Exchange Select 44-503A473**

***Active ingredients (in each caplet)  
(Daytime Cold & Flu Severe)***

Acetaminophen 325 mg  
Dextromethorphan HBr 10 mg  
Guaifenesin 200 mg  
Phenylephrine HCl 5 mg

***Purpose***

Pain reliever/fever reducer  
Cough suppressant  
Expectorant  
Nasal decongestant

***Active ingredients (in each caplet)  
(Nighttime Cold & Flu Severe)***

Acetaminophen 325 mg  
Chlorpheniramine maleate 2 mg  
Dextromethorphan HBr 10 mg  
Phenylephrine HCl 5 mg

***Purpose***

Pain reliever/fever reducer  
Antihistamine  
Cough suppressant  
Nasal decongestant

***Uses***

- temporarily relieves these common cold and flu symptoms:
  - cough
  - sore throat
  - headache
  - nasal congestion
  - minor aches and pains
  - sinus congestion and pressure (*Nighttime only*)
  - sneezing and runny nose (*Nighttime only*)
- helps clear nasal passages (*Nighttime only*)
- relieves cough to help you sleep (*Nighttime only*)
- help loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive (*Daytime*)

*only*)

- 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
- 3 or more alcoholic drinks every day while using this product
- with other drugs containing acetaminophen

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

### **Ask a doctor or pharmacist before use if you are**

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers (**Nighttime only**)

### **When using this product**

- **do not exceed recommended dosage**
- excitability may occur, especially in children (**Nighttime only**)
- marked drowsiness may occur (**Nighttime only**)
- avoid alcoholic beverages (**Nighttime only**)
- use caution when driving a motor vehicle or operating machinery (**Nighttime only**)
- alcohol, sedatives, and tranquilizers may increase drowsiness (**Nighttime only**)

**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.

**Read each section carefully. Do not take DAYTIME and NIGHTTIME products at the same time.**

**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°F)
- see end flap for expiration date and lot number

**Inactive ingredients (Daytime only)**

corn starch, crospovidone, D&C yellow #10 aluminum lake, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

**Inactive ingredients (Nighttime only)**

corn starch, crospovidone, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, 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 + FLU SEVERE Day & Tylenol® COLD + FLU SEVERE Night\*

**DAY & NIGHTTIME**

**COLD & FLU**

**SEVERE**

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**Acetaminophen**

Dextromethorphan HBr

Guaifenesin

Phenylephrine HCl

• Pain Reliever/Fever Reducer

• Cough Suppressant

• Expectorant

• Nasal Decongestant

**DAY**

**16** Caplets

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**Acetaminophen**

Chlorpheniramine maleate

Dextromethorphan HBr

Phenylephrine HCl

• Pain Reliever/Fever Reducer

• Antihistamine

• Cough Suppressant

• Nasal Decongestant

**NIGHT**

**8** Caplets

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**24** TOTAL CAPLETS

Pseudoephedrine Free

**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 + FLU SEVERE Day & Tylenol® COLD + FLU SEVERE Night.

50844 REV0718A50347308

**"SATISFACTION GUARANTEED OR YOUR MONEY BACK"**

Manufactured For Your Military Exchanges

Distributed by: LNK International, Inc.,

Hauppauge, NY 11788 1-800-426-9391



Exchange Select 44-503A473

## COLD AND FLU SEVERE, DAY AND NIGHTTIME

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, guaifenesin, phenylephrine hcl kit

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55301-573
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55301-573-08	1 in 1 CARTON; Type 0: Not a Combination Product	08/04/2005	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 BLISTER PACK	16
Part 2	1 BLISTER PACK	8

### Part 1 of 2

## COLD AND FLU DAY, SEVERE

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film 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
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

## Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPVIDONE (UNII: 2S7830E561)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

## Product Characteristics

Color	YELLOW	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	44;503
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	08/04/2005	

## Part 2 of 2

### COLD AND FLU NIGHTTIME, SEVERE

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl tablet, film 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
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
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPVIDONE (UNII: 2S7830E561)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

#### Product Characteristics

<b>Color</b>	BLUE	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	44;473
<b>Contains</b>			

**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	07/21/2005	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	08/04/2005	

**Labeler** - ARMY AND AIR FORCE EXCHANGE SERVICE (001695568)

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(5530 1-573)

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(5530 1-573)

Revised: 11/2019

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