

**HEAD CONGESTION COLD RELIEF - acetaminophen, chlorpheniramine maleate,  
dextromethorphan hbr, phenylephrine hcl tablet, film coated  
WOONSOCKET PRESCRIPTION CENTER, INCORPORATED**

*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.*

-----

***Drug Facts***

***Active ingredients***

***(in each caplet)***

Acetaminophen 325 mg

Chlorpheniramine maleate 2 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

***Purpose***

Pain reliever

Antihistamine

Cough suppressant

Nasal decongestant

***Uses***

- temporarily relieves these common cold symptoms:
- minor aches and pains
- headache
- cough
- sneezing and runny nose
- nasal congestion
- sinus congestion and pressure
- sore throat
- helps clear nasal passages
- relieves cough to help you sleep

***Warnings***

**Liver warning:**

This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 12 caplets 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

**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, ask a doctor or pharmacist before taking this product.

**Ask a doctor before use if you have**

- liver disease
- diabetes
- heart disease
- high blood pressure
- glaucoma
- thyroid disease
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

**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**
- avoid alcoholic drinks
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- excitability may occur, especially in children
- 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
- 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.**

**Overdose warning:** Taking more than the recommended dose (overdose) may cause liver damage. In

case of overdose, get medical help or contact a Poison Control Center right away. 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)**
- 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 12 caplets in 24 hours
- children under 12 years: do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage

### ***Other information***

- store at controlled room temperature 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

### ***Inactive ingredients***

corn starch, FD&C blue #1, FD&C blue #2, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silica gel, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

### ***Questions or comments?***

**1-800-426-9391**

## **PRODUCT PACKAGING**

The product packaging shown below represents a sample of that currently in use. Additional packaging may also be available.

**CVS®**

**pharmacy**

Compare to the active

ingredients of Tylenol® Cold

Head Congestion Nighttime\*

**See New Warnings**

**Information**

**HEAD CONGESTION**

**COLD RELIEF**

**PAIN RELIEVER, NASAL DECONGESTANT,**

**COUGH SUPPRESSANT, ANTIHISTAMINE**

**NIGHTTIME**

**TO LET YOU SLEEP**

**CONTAINS 4 MEDICINES**

Headache Pain -

- Acetaminophen

Sore Throat -

Nasal Congestion - Phenylephrine HCl

Coughing - Dextromethorphan HBr

Runny Nose - Chlorpheniramine Maleate

12 COOL ICE® CAPLETS

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

50844

REV1009A47302

Distributed by:

CVS Pharmacy, Inc.

One CVS Drive

Woonsocket, RI 02895

© 2010 CVS/pharmacy

www.cvs.com

1-800-shop-CVS

This product is not manufactured or distributed by Michel Consumer Healthcare, owner of the registered trademark, Tylenol®. © 2010 CVS/pharmacy. Woonsocket, RI 02895. Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895. www.cvs.com 1-800-shop-CVS

**CVS Quality**  
A COMMITMENT TO EXCELLENCE  
GUARANTEE

Does not contain Pseudoephedrine

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

NOT LABELED FOR INDIVIDUAL SALE

Compare to the active ingredients of Tylenol® Cold Head Congestion Nighttime®. See New Warnings Information

**CVS pharmacy**

**HEAD CONGESTION COLD RELIEF**

**PAIN RELIEVER, NASAL DECONGESTANT, COUGH SUPPRESSANT, ANTIHISTAMINE**

**NIGHTTIME TO LET YOU SLEEP**  
CONTAINS 4 MEDICINES

Headache Pain  
Sore Throat  
Nasal Congestion - Phenylephrine HCl  
Coughing - Dextromethorphan HBr  
Runny Nose - Chlorpheniramine Maleate

12 COOL ICE® CAPLETS

CVS PHARMACIST • GENIUM RECOMMEND

DG8025r1  
2 3/4 x 7/8 x 3 1/4

**Drug Facts (continued)**

**Warnings**

- liver damage may occur if you take more than 12 caplets 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

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, masser, or vomiting, consult a doctor promptly.

**Do not use**

- with any other drug containing acetaminophen (prescription or over-the-counter)
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or other 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.

**Ask a doctor before use if you have**

- liver disease
- high blood pressure
- kidney disease
- trouble urinating due to an enlarged prostate gland
- benzhexol, phenol, or any other prescription or over-the-counter 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

**Drug Facts (continued)**

**Warnings**

- drowsiness, dizziness, or sleepiness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- fever, sore throat, or other symptoms occur
- rash, hives, or other allergic reactions occur within 30 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.**

**Overdose warning:** Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. 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)
- adults and children 12 years and over: take 2 caplets every 4 hours

**Drug Facts (continued)**

**Other information**

- Store at controlled room temperature 15-30°C (59-86°F)
- See end flap for expiration date and lot number.

**Inactive ingredients** corn starch, FD&C Blue #1, FD&C Blue #2, flavor, magnesium stearate, microcrystalline cellulose.

**Drug Facts (continued)**

polyethylene glycol, polyvinyl alcohol, povidone, silica gel, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

**Questions or comments?**  
1-800-426-9391

No Print Area  
Lot no. and expiration date

B-0231-473C-02HCIN  
REV1009A47302

HEAD CONGESTION COLD RELIEF

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59779-473
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Acetaminophen</b> (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	325 mg
<b>Chlorpheniramine Maleate</b> (UNII: V1Q0O9OJ9Z) (Chlorpheniramine - UNII:3U6IO1965U)	Chlorpheniramine Maleate	2 mg
<b>Dextromethorphan Hydrobromide</b> (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	10 mg
<b>Phenylephrine Hydrochloride</b> (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>Starch, Corn</b> (UNII: O8232NY3SJ)	
<b>Fd&amp;c Blue No. 1</b> (UNII: H3R47K3TBD)	
<b>Fd&amp;c Blue No. 2</b> (UNII: L06K8R7DQK)	
<b>Magnesium Stearate</b> (UNII: 70097M6I30)	
<b>Cellulose, Microcrystalline</b> (UNII: OP1R32D61U)	
<b>Polyethylene Glycol</b> (UNII: 3WJQ0SDW1A)	
<b>Polyvinyl Alcohol</b> (UNII: 532B59J990)	
<b>Povidone</b> (UNII: FZ989GH94E)	
<b>Silicon Dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>Stearic Acid</b> (UNII: 4ELV7Z65AP)	
<b>Sucralose</b> (UNII: 96K6UQ3ZD4)	
<b>Talc</b> (UNII: 7SEV7J4R1U)	
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	BLUE	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	17mm
<b>Flavor</b>	MENTHOL (Cool Ice)	<b>Imprint Code</b>	44;473
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-473-01	1 in 1 CARTON		
1		12 in 1 BLISTER PACK		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	07/21/2005	

**Labeler** - WOONSOCKET PRESCRIPTION CENTER, INCORPORATED (062312574)

**Registrant** - L.N.K. International, Inc. (832867837)

## Establishment

Name	Address	ID/FEI	Business Operations
L.N.K. International, Inc		832867894	MANUFACTURE

Revised: 8/2010

WOONSOCKET PRESCRIPTION CENTER, INCORPORATED