HEAD CONGESTION COLD RELIEF - acetaminophen, 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

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves theses common cold symptoms:
- minor aches and pains
- headache
- nasal congestion
- cough
- sore throat
- sinus congestion and pressure
- helps clear nasal passages

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 vommiting, 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.

Ask a doctor before use if you have
- diabetes
- thyroid disease
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- heart disease
- liver disease
- 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
- 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, croscarmellose sodium, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silica gel, stearic acid, sucralose, talc, titanium dioxide

Questions or comments?

Call 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 Daytime*

See New Warnings

Information

HEAD CONGESTION

COLD RELIEF

PAIN RELIEVER, NASAL DECONGESTANT,

COUGH SUPPRESSANT

DAYTIME

NON-DROWSY

CONTAINS 3 MEDICINES

Headache Pain -

- Acetaminophen

Sore Throat -

Nasal Congestion - Phenylephrine HCl

Coughing - Dextromethorphan HBr

12 COOL ICE® CAPLETS

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

50844 REV1009A47002

Distributed by: **CVS Pharmacy, Inc.**

One CVS Drive, Woonsocket, RI 02895

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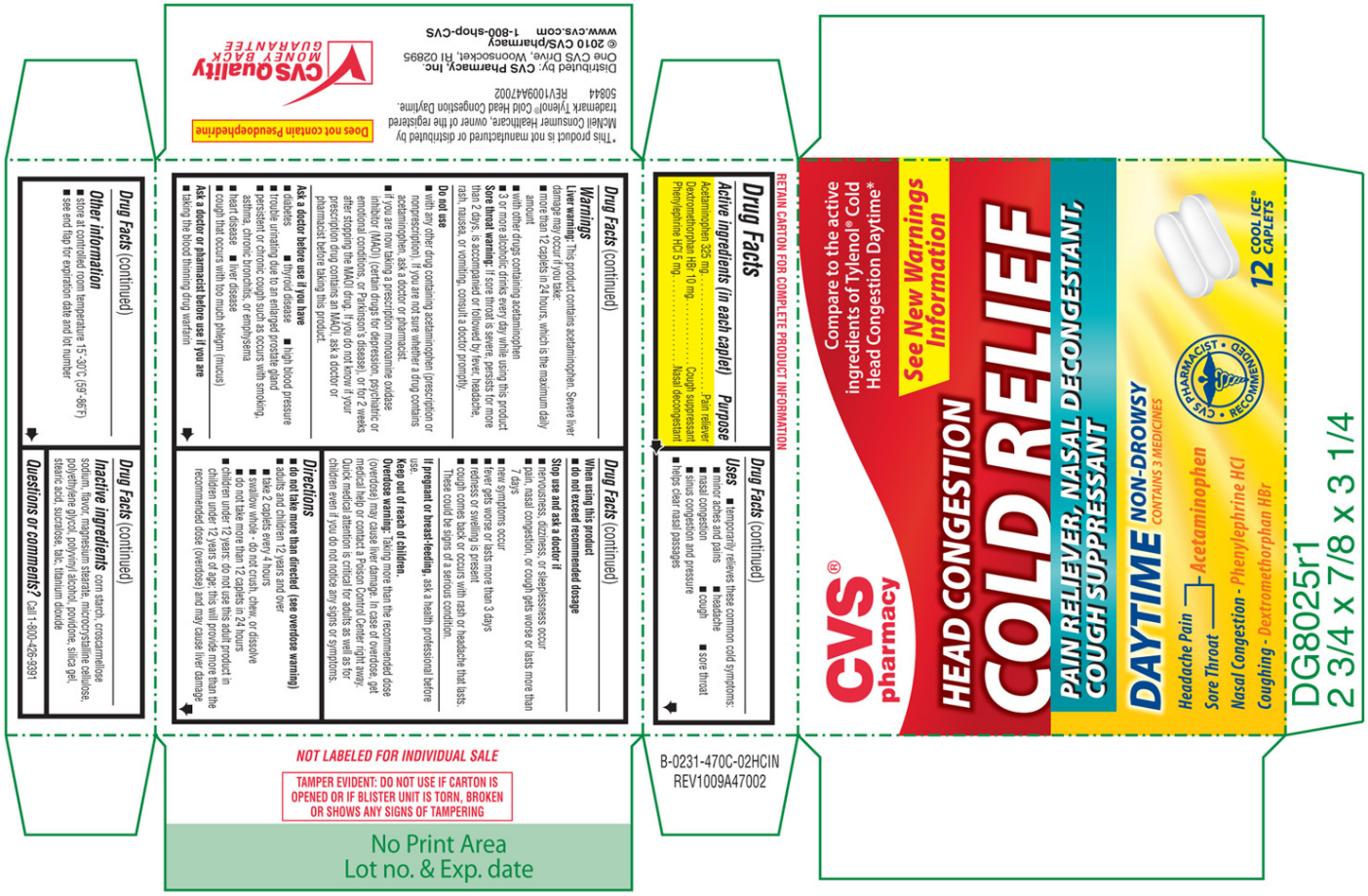
www.cvs.com **1-800-shop-CVS**



HEAD CONGESTION COLD RELIEF

acetaminophen, dextromethorphan hbr, phenylephrine hcl tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59779-470
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**
Starch, Corn (UNII: O8232NY3SJ)	
Croscarmellose Sodium (UNII: M28OL1HH48)	
Magnesium Stearate (UNII: 70097M6I30)	
Cellulose, Microcrystalline (UNII: OP1R32D61U)	
Polyethylene Glycol (UNII: 3WJQ0SDW1A)	
Polyvinyl Alcohol (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	CAPSULE	**Size**	17mm
Flavor	MENTHOL (Cool Flavored)	**Imprint Code**	44;470
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:59779-470-01	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	06/11/2006	

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