# MULTI-SYMPTOM DAYTIME COLD - acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled COSTCO WHOLESALE CORPORATION

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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#### **Drug Facts**

#### 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 12 gelcaps 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 presciption 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

- liver disease
- diabetes
- heart disease
- thyroid disease
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- high blood pressure
- 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
- new symptoms occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- 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 gelcaps every 4 hours
- do not take more than 12 gelcaps 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**

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?

1-800-774-2678

#### PRODUCT PACKAGING

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

#### **KIRKLAND**

Signature<sup>TM</sup>

COMPARE TO TYLENOL®

COLD MULTI-SYMPTOMS DAYTIME

active ingredients\*

NDC 63981-560-46

ITEM #532129

**DAYTIME** 

**NON-DROWSY** 

COLD

**MULTI-SYMPTOM** 

Acetaminophen 325 mg,

#### Dextromethorphan HBr 10 mg, Phenylephrine HCl 5 mg

Pain Reliever/Fever Reducer,

Nasal Decongestant, Cough Suppressant

#### **See New Warnings Information**

Temporarily Relieves:

√ Fever / Headache / Sore Throat

 $\sqrt{\text{Nasal Congestion}}$ 

√ Coughing

**Actual Size** 

96

#### Rapid Release

#### Gelcaps

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

50844 ORG100956046

Manufactured by: LNK INTERNATIONAL, INC.

60 Arkay Drive, Hauppauge, NY 11788 USA

For Costco Wholesale Corporation

P.O. Box 34535

Seattle, WA 98124-1535 USA

1-800-774-2678

www.costco.com



#### MULTI-SYMPTOM DAYTIME COLD

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

#### **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63981-560
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Acetaminophen (UNII: 36209ITL9D) (Acetaminophen - UNII:36209ITL9D)	Acetaminophen	325 mg		
<b>Dextromethorphan Hydrobromide</b> (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
Croscarmellose Sodium (UNII: M28 OL 1HH48)	
Crospovidone (UNII: 68401960MK)	
D&c Red No. 28 (UNII: 767IP0 Y5NH)	
Fd&c Blue No. 1 (UNII: H3R47K3TBD)	
Fd&c Red No. 40 (UNII: WZB9127XOA)	
Gelatin (UNII: 2G86QN327L)	
Hydroxypropyl Cellulose (UNII: RFW2ET671P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
Ferrosoferric Oxide (UNII: XM0M87F357)	
Ferric Oxide Yellow (UNII: EX438O2MRT)	
Magnesium Stearate (UNII: 70097M6I30)	
Cellulose, Microcrystalline (UNII: OP1R32D61U)	
Polyethylene Glycol (UNII: 3WJQ0SDW1A)	
Povidone (UNII: FZ989GH94E)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Titanium Dioxide (UNII: 15FIX9 V2JP)	

Product Characteristics			
Color	RED (Lavender)	Score	no score
Shape	CAPSULE	Size	19 mm
Flavor		Imprint Code	44;560
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:63981-560-46	1 in 1 CARTON		
1	96 in 1 BLISTER PACK		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	03/29/2008	

## Labeler - COSTCO WHOLESALE CORPORATION (103391843)

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

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

Revised: 9/2010 COSTCO WHOLESALE CORPORATION