COLD RELIEF MULTI-SYMPTOM- acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl
L.N.K. International, Inc.

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.

Quality Plus 44-470C473-08

Active ingredients (in each caplet)
(Daytime Cold Multi-Symptom)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Nasal decongestant

Active ingredients (in each caplet)
(Nighttime Cold Multi-Symptom)

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
  - sneezing and runny nose ***(Nighttime only)***
- helps clear nasal passages
- relieves cough to help you sleep ***(Nighttime only)***
- promotes nasal and sinus drainage ***(Daytime only)***
- temporarily reduces fever

Warnings

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

- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product
- more than 4,000 mg in 24 hours, which is the maximum daily amount

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

If taking NIGHTTIME and DAYTIME products, carefully read each section to ensure correct dosing.

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, croscarmellose sodium, crospovidone, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silica gel, 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, silica gel, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

Questions or comments?

1-800-426-9391

Principal Display Panel

QUALITY
+ PLUS

NDC 50844-529-08

***Compare to active ingredients in Tylenol® COLD MAX Day & Tylenol® Cold Multi-Symptom Night**

MULTI-SYMPTOM
COLD RELIEF

Acetaminophen, Dextromethorphan HBr, Phenylephrine HCl PAIN RELIEVER/FEVER REDUCER COUGH SUPPRESSANT, NASAL DECONGESTANT ***NON-DROWSY*** **12** Caplets	**Acetaminophen,** Chlorpheniramine maleate, Dextromethorphan HBr, Phenylephrine HCl PAIN RELIEVER/FEVER REDUCER, ANTIHISTAMINE, COUGH SUPPRESSANT, NASAL DECONGESTANT ***12*** Caplets

24 Total Caplets

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 McNeil Consumer Healthcare, owner of the registered trademark Tylenol® COLD MAX Day & Tylenol® Cold Multi-Symptom Night.
50844 REV0316A47047308
Distributed by
LNK INTERNATIONAL, INC.
60 Arkay Drive, Hauppauge, NY 11788
USA

QUALITY PLUS

DAY/NIGHT COMBO

MULTI-SYMPTOM COLD RELIEF

QUALITY PLUS

NDC 50844-529-08

*Compare to active ingredients in Tylenol® COLD MAX Day & Tylenol® Cold Multi-Symptom Night

MULTI-SYMPTOM COLD RELIEF

Acetaminophen,
Dextromethorphan HBr,
Phenylephrine HCl

PAIN RELIEVER/FEVER REDUCER,
COUGH SUPPRESSANT,
NASAL DECONGESTANT

NON-DROWSY

ACTUAL SIZE

12 Caplets

Acetaminophen,
Chlorpheniramine maleate,
Dextromethorphan HBr,
Phenylephrine HCl

PAIN RELIEVER/FEVER REDUCER,
ANTIHISTAMINE,
COUGH SUPPRESSANT,
NASAL DECONGESTANT

ACTUAL SIZE

12 Caplets

24 Total Caplets

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0 50844 52908 3

No Print / No Varnish
Lot no. & Exp. date

Drug Facts (continued)

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

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

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Distributed by
LNK INTERNATIONAL, INC.
60 Arkay Drive, Hauppauge, NY 11788
USA

B-1603-470C473-08R
REV0316A47047308

Drug Facts

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Active ingredients (in each caplet) Purpose (Daytime Cold Multi-Symptom)

Acetaminophen 325 mg ... Pain reliever/fever reducer
Dextromethorphan HBr 10 mg ... Cough suppressant
Phenylephrine HCl 5 mg ... Nasal decongestant

Active ingredients (in each caplet) Purpose (Nighttime Cold Multi-Symptom)

Acetaminophen 325 mg ... Pain reliever/fever reducer
Chlorpheniramine maleate 2 mg ... Antihistamine
Dextromethorphan HBr 10 mg ... Cough suppressant
Phenylephrine HCl 5 mg ... 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 ■ sneezing and runny nose ***(Nighttime only)***
- helps clear nasal passages
- relieves cough to help you sleep ***(Nighttime only)***
- promotes nasal and sinus drainage ***(Daytime only)***
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen.

Drug Facts (continued)

Severe liver damage may occur if you take:

- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product
- more than 4,000 mg in 24 hours, which is the maximum daily amount

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

Drug Facts (continued)

smoking, asthma, or emphysema
- difficulty in urination due to enlargement of the prostate gland
- 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)***
- be careful 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

Drug Facts (continued)

If taking NIGHTTIME and DAYTIME products, carefully read each section to ensure correct dosing.

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**

Drug Facts (continued)

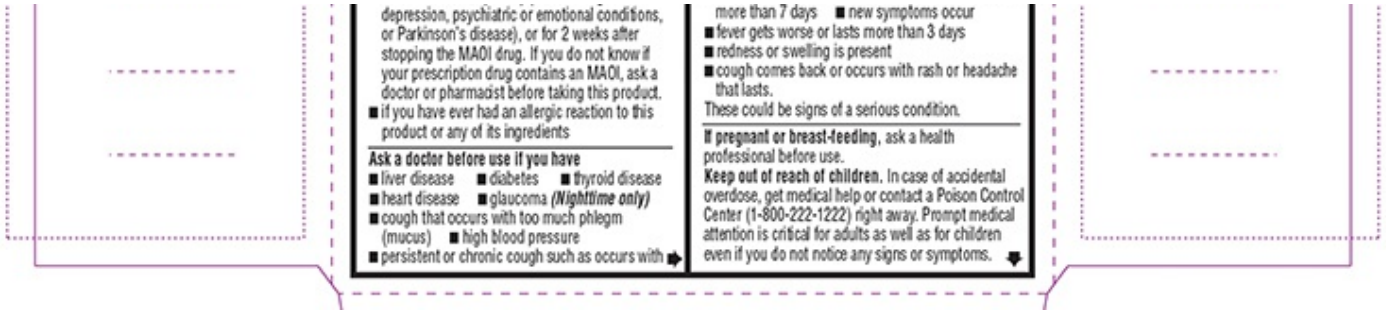
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients (Daytime only)

corn starch, croscarmellose sodium, crospovidone, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silica gel, 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



Quality Plus 44-470C473-08

COLD RELIEF MULTI-SYMPTOM

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50844-529

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:50844-529-08	1 in 1 CARTON; Type 0: Not a Combination Product	07/21/2005	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BLISTER PACK	12
Part 2	1 BLISTER PACK	12

Part 1 of 2

COLD RELIEF DAYTIME

acetaminophen, 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
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**
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPOVIDONE (UNII: 2S7830E561)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
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)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	OVAL	**Size**	17mm
Flavor	MINT	**Imprint Code**	44;470
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
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	07/15/2005	

Part 2 of 2

COLD RELIEF NIGHTTIME

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
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPOVIDONE (UNII: 2S7830E561)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
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

Color	BLUE	**Score**	no score
Shape	OVAL	**Size**	17mm
Flavor	MINT	**Imprint Code**	44;473
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	07/21/2005	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	07/21/2005	

Labeler - L.N.K. International, Inc. (038154464)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(50844-529)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(50844-529)

Revised: 5/2019 L.N.K. International, Inc.