#### DAYTIME COLD, NIGHTTIME COLD MULTI-SYMPTOM- acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl United Natural Foods, Inc. dba UNFI

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#### Equaline 44-470C473C

#### 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
- 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 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**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)
- 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 overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

# 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

- each caplet contains: sodium 3 mg (Nighttime only)
- 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, silicon dioxide, 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?**

1-855-423-2630

# Principal Display Panel

#### **EQUAL**INE<sup>®</sup>

NDC 41163-529-08

multi-symptom daytime cold acetaminophen (pain reliever/fever reducer) dextromethorphan HBr (cough suppressant) phenylephrine HCI (nasal decongestant) relieves: • fever/headache/sore throat • cough • nasal congestion PSEUDOEPHEDRINE FREE	multi-symptom <b>nighttime</b> <b>cold</b> <b>acetaminophen</b> (pain reliever/fever reducer) chlorpheniramine maleate (antihistamine) dextromethorphan HBr (cough suppressant) phenylephrine HCl (nasal decongestant) <i>relieves:</i> • fever/headache/sore throat • runny nose • cough • nasal congestion PSEUDOEPHEDRINE FREE
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actual size

24 caplets with cool blast flavor = 12 daytime + 12 nighttime

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

#### **PARENTS:**

Learn about teen medicine abuse www.StopMedicineAbuse.org

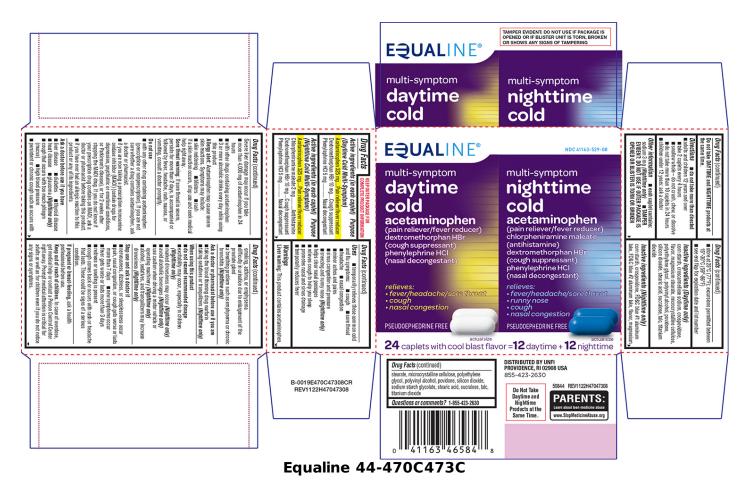
Do Not Take Daytime and Nighttime Products at the

#### Same Time.

# DISTRIBUTED BY UNFI **PROVIDENCE, RI 02908 USA**

855-423-2630

#### 50844 REV1122H47047308



#### DAYTIME COLD, NIGHTTIME COLD MULTI-SYMPTOM acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl kit **Product Information Product Type** HUMAN OTC DRUG Item Code (Source) NDC:41163-529 Packaging **Marketing Start** Marketing End **Item Code Package Description** # Date Date 1 NDC:41163-529- 1 in 1 CARTON; Type 0: Not a Combination 07/21/2005 08 Product **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

# DAYTIME COLD MULTI-SYMPTOM

acetaminophen, dextromethorphan hbr, phenylephrine hcl tablet, film coated

#### **Product Information**

Route of Administration ORAL

Active Ingredient/Active Moiety					
Ingredient Name	<b>Basis of Strength</b>	Strength			
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D)	ACETAMINOPHEN	325 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		
STARCH, CORN (UNII: 08232NY3SJ)			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQOSDW1A)			
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)			
POVIDONE, UNSPECIFIED (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	OVAL	Size	17mm	
Flavor	MENTHOL	Imprint Code	44;470	
Contains				

Packaging

" Code	Pac	kage Description	Mark	eting Start Date		ting End ate
1	12 in 1 BLISTER P Product	ACK; Type 0: Not a Combination				
	Troduct					
	ng Informat					
Marketir Categor		ation Number or Monograph Citation	Mai	rketing Start Date		eting End Date
OTC Monograp	-		07/15/		-	
Part 2 of	F <b>2</b>					
NIGHTTI		MULTI-SYMPTOM				
-			rahan h	hr phonyloph	ring halt	ablat film
•	nen, chiorphenir	ramine maleate, dextrometho	rpnan n	ibr, phenylepr	irine nci t	ablet, film
coated						
Due des 14	6					
	formation					
Route of Ad	ministration	ORAL				
Active Ingi	redient/Active	•				
	•			Basis of St	-	Strengt
		L9D) (ACETAMINOPHEN - UNII:36209 (UNII: V1Q0090J9Z) (CHLORPHENIR		ACETAMINOPHEN CHLORPHENIRAM		325 mg
UNII: 3U6IO1965				MALEATE		2 mg
		BROMIDE (UNII: 9D2RTI9KYH)				
(DEXTROMETHORPHAN - UNII:7355X3ROTS) PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPH				DEXTROMETHOR HYDROBROMIDE	PHAN	10 mg
PHENYLEPHRI UNII:1WS297W6		X3ROTS)	RINE -			10 mg 5 mg
		X3ROTS)	RINE -	HYDROBROMIDE PHENYLEPHRINE		
UNII:1WS297W6	5MV)	X3ROTS)	RINE -	HYDROBROMIDE PHENYLEPHRINE		
	5MV)	X3ROTS)	RINE -	HYDROBROMIDE PHENYLEPHRINE	:	
UNII:1W5297W6	5MV)	X3ROTS) NDE (UNII: 04JA59TNSJ) (PHENYLEPH Ingredient Name	RINE -	HYDROBROMIDE PHENYLEPHRINE	:	5 mg
UNII:1W5297W6 Inactive In STARCH, COR	5MV) I <b>gredients</b> I <b>N</b> (UNII: 08232NY3	X3ROTS) NDE (UNII: 04JA59TNSJ) (PHENYLEPH Ingredient Name	RINE -	HYDROBROMIDE PHENYLEPHRINE	:	5 mg
UNII: 1W5 297W6 Inactive In STARCH, COR CROSPOVIDO	I <b>gredients</b> N (UNII: 08232NY3 NE, UNSPECIFIED	X3ROTS) NDE (UNII: 04JA59TNSJ) (PHENYLEPH Ingredient Name SJ)	RINE -	HYDROBROMIDE PHENYLEPHRINE	:	5 mg
UNII:1W5297W6 Inactive In STARCH, COR CROSPOVIDO FD&C BLUE N	SMV) Igredients IN (UNII: 08232NY33 NE, UNSPECIFIED IO. 1 ALUMINUM L	X3ROTS) NDE (UNII: 04JA59TNSJ) (PHENYLEPH Ingredient Name SJ) (UNII: 2S7830E561)	RINE -	HYDROBROMIDE PHENYLEPHRINE	:	5 mg
UNII: 1W5297W6 Inactive In STARCH, COR CROSPOVIDO FD&C BLUE N FD&C BLUE N	SMV) Igredients IN (UNII: 08232NY33 NE, UNSPECIFIED IO. 1 ALUMINUM L	X3ROTS) XIDE (UNII: 04JA59TNSJ) (PHENYLEPH Ingredient Name SJ) (UNII: 2S7830E561) AKE (UNII: J9EQA3S2JM) AKE (UNII: 4AQJ3LG584)	RINE -	HYDROBROMIDE PHENYLEPHRINE	:	5 mg
UNII: 1WS 297W6 Inactive In STARCH, COR CROSPOVIDO FD&C BLUE N FD&C BLUE N MAGNESIUM S	SMV) Igredients IN (UNII: 08232NY33 NE, UNSPECIFIED IO. 1 ALUMINUM L IO. 2 ALUMINUM L STEARATE (UNII: 70	X3ROTS) XIDE (UNII: 04JA59TNSJ) (PHENYLEPH Ingredient Name SJ) (UNII: 2S7830E561) AKE (UNII: J9EQA3S2JM) AKE (UNII: 4AQJ3LG584)	RINE -	HYDROBROMIDE PHENYLEPHRINE	:	5 mg
UNII: 1WS 297W6 Inactive In STARCH, COR CROSPOVIDO FD&C BLUE N FD&C BLUE N MAGNESIUM S MICROCRYSTA	SMV) SMV) SM (UNII: 08232NY33 NE, UNSPECIFIED IO. 1 ALUMINUM L IO. 2 ALUMINUM L STEARATE (UNII: 70 ALLINE CELLULOS NE GLYCOL, UNSP	X3ROTS) XIDE (UNII: 04JA59TNSJ) (PHENYLEPH Ingredient Name SJ) (UNII: 2S7830E561) AKE (UNII: J9EQA3S2JM) AKE (UNII: 4AQJ3LG584) 0097M6I30) SE (UNII: OP1R32D61U) PECIFIED (UNII: 3WJQ0SDW1A)	RINE -	HYDROBROMIDE PHENYLEPHRINE	:	5 mg
UNII: 1WS 297W6 Inactive In STARCH, COR CROSPOVIDO FD&C BLUE N FD&C BLUE N MAGNESIUM S MICROCRYSTA	SMV) SMV) SM (UNII: 08232NY33 NE, UNSPECIFIED IO. 1 ALUMINUM L IO. 2 ALUMINUM L STEARATE (UNII: 70 ALLINE CELLULOS NE GLYCOL, UNSP	X3ROTS) <b>Ingredient Name</b> SJ) (UNII: 2S7830E561) <b>AKE</b> (UNII: J9EQA3S2JM) <b>AKE</b> (UNII: 4AQJ3LG584) 0097M6I30) <b>SE</b> (UNII: OP1R32D61U)	RINE -	HYDROBROMIDE PHENYLEPHRINE		5 mg
UNII: 1WS 297W6 Inactive In STARCH, COR CROSPOVIDO FD&C BLUE N FD&C BLUE N MAGNESIUM S MICROCRYST POLYETHYLEN POLYVINYL AL POLYVINYL AL	Igredients In (UNII: 08232NY33 NE, UNSPECIFIED IO. 1 ALUMINUM L IO. 2 ALUMINUM L STEARATE (UNII: 70 ALLINE CELLULOS NE GLYCOL, UNSPEC ISPECIFIED (UNII:	X3ROTS) XIDE (UNII: 04JA59TNSJ) (PHENYLEPH Ingredient Name SJ) (UNII: 2S7830E561) AKE (UNII: J9EQA3S2JM) AKE (UNII: 4AQJ3LG584) 0097M6I30) SE (UNII: OP1R32D61U) PECIFIED (UNII: 3WJQ0SDW1A) IFIED (UNII: 532B59J990) FZ 989GH94E)	RINE -	HYDROBROMIDE PHENYLEPHRINE		5 mg
UNII: 1WS 297W6 Inactive In STARCH, COR CROSPOVIDO FD&C BLUE N FD&C BLUE N MAGNESIUM S MICROCRYST POLYETHYLEN POLYVINYL AL POVIDONE, UI SILICON DIOX	SMV) agredients N (UNII: 08232NY33 NE, UNSPECIFIED IO. 1 ALUMINUM L IO. 2 ALUMINUM L STEARATE (UNII: 70 ALLINE CELLULOS NE GLYCOL, UNSPEC NSPECIFIED (UNII: KIDE (UNII: ETJ7Z6X)	X3ROTS) XIDE (UNII: 04JA59TNSJ) (PHENYLEPH Ingredient Name SJ) (UNII: 2S7830E561) AKE (UNII: J9EQA3S2JM) AKE (UNII: 4AQJ3LG584) 0097M6I30) E (UNII: 0P1R32D61U) PECIFIED (UNII: 3WJQ0SDW1A) IFIED (UNII: 532B59J990) FZ989GH94E) BU4)	RINE -	HYDROBROMIDE PHENYLEPHRINE		5 mg
JNII: 1W5 297W6 Inactive In STARCH, COR CROSPOVIDO FD&C BLUE N FD&C BLUE N MAGNESIUM S MICROCRYST POLYETHYLEN POLYVINYL AL POLYVINYL AL POLYVINYL AL POVIDONE, UI SILICON DIOX	SMV) agredients N (UNII: 08232NY33 NE, UNSPECIFIED IO. 1 ALUMINUM L IO. 2 ALUMINUM L STEARATE (UNII: 70 ALLINE CELLULOS NE GLYCOL, UNSPEC NSPECIFIED (UNII: CIDE (UNII: ETJ7Z6X) RCH GLYCOLATE T	X3ROTS) XIDE (UNII: 04JA59TNSJ) (PHENYLEPH Ingredient Name SJ) (UNII: 2S7830E561) AKE (UNII: J9EQA3S2JM) AKE (UNII: 4AQJ3LG584) 0097M6I30) SE (UNII: 0P1R32D61U) PECIFIED (UNII: 3WJQ0SDWIA) IFIED (UNII: 532B59J990) FZ989GH94E) BU4) YPE A POTATO (UNII: 5856J3G2A2)	RINE -	HYDROBROMIDE PHENYLEPHRINE		5 mg
UNII: 1WS 297WG Inactive In STARCH, COR CROSPOVIDO FD&C BLUE N FD&C BLUE N MAGNESIUM S MICROCRYST POLYETHYLEN POLYETHYLEN POLYVINYL AL POVIDONE, UI SILICON DIOX SODIUM STAR STEARIC ACID	SMV) agredients N (UNII: 08232NY33 NE, UNSPECIFIED IO. 1 ALUMINUM L IO. 2 ALUMINUM L STEARATE (UNII: 70 ALLINE CELLULOS NE GLYCOL, UNSPEC NSPECIFIED (UNII: KIDE (UNII: ETJ7Z6X)	X3ROTS) XIDE (UNII: 04JA59TNSJ) (PHENYLEPH Ingredient Name SJ) (UNII: 2S7830E561) AKE (UNII: J9EQA3S2JM) AKE (UNII: J9EQA3S2JM) AKE (UNII: 4AQJ3LG584) 0097M6I30) SE (UNII: 0P1R32D61U) PECIFIED (UNII: 3WJQ0SDW1A) IFIED (UNII: 532B59J990) FZ989GH94E) BU4) TYPE A POTATO (UNII: 5856J3G2A2; P)	RINE -	HYDROBROMIDE PHENYLEPHRINE		5 mg

			5FIX9\/2IP)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)							
Pro	duct Ch	aracteris	tics				
Colo	r		blue Score r			no score	
Shaj	pe		OVAL	Size	Size		
Flav	or		MENTHOL	Imprint Cod	e	44;473	
Cont	tains						
_							
Pac	kaging						
μ	ltem	Package Description			Marketing Start	Marketing End	
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Labeler - United Natural Foods, Inc. dba UNFI (943556183)

Establishment						
Name	Address	ID/FE	I	Business Operations		
LNK International, Inc.		83286783	7 manufactur	e(41163-529) , pack(41163-529)		
Establishment						
Name	Ad	dress	ID/FEI	<b>Business Operations</b>		
LNK International, Inc.			832867894	manufacture(41163-529)		

# Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		117025878	manufacture(41163-529)