# SEVERE COLD AND FLU PLUS CONGESTION- acetaminophen, dextromethorphan hbr, doxylamine succinate, guaifenesin, phenylephrine hcl COSTCO WHOLESALE CORPORATION

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Kirkland 44-795796-81

## Day

# Active ingredients (in each caplet)

Acetaminophen 325 mg Dextromethorphan HBr 10 mg Guaifenesin 200 mg Phenylephrine HCl 5 mg

# Purpose

Pain reliever/fever reducer Cough suppressant Expectorant Nasal decongestant

#### Uses

- temporarily relieves common cold and flu symptoms:
  - nasal congestion
  - sore throat
  - minor aches and pains
  - headache
  - sinus congestion and pressure
  - cough due to minor throat and bronchial irritation
  - reduces swelling of nasal passages
- temporarily reduces fever
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

# 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:

- blisters
- rash
- skin reddening

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
- high blood pressure
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, 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.

# When using this product

do not exceed recommended dosage.

#### Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- redness or swelling is present
- 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
- 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.

# **Directions**

- do not take more than directed
- do not take more than 8 caplets in 24 hours
- adults and children 12 years and over: take 2 caplets with water every 4 hours
- children under 12 years: ask a doctor

#### Other information

- each caplet contains: sodium 3 mg
- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- see end flap for expiration date and lot number
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

# Inactive ingredients

benzyl alcohol, corn starch, crospovidone, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polysorbate 80, polyvinyl alcohol, povidone, propylene glycol, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

#### Questions or comments?

1-800-426-9391

## **Night**

# Active ingredients (in each caplet)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Doxylamine succinate 6.25 mg
Phenylephrine HCl 5 mg

# **Purpose**

Pain reliever/fever reducer Cough suppressant Antihistamine Nasal decongestant

#### Uses

- temporarily relieves common cold and flu symptoms:
  - nasal congestion
  - sore throat
  - minor aches and pains
  - headache
  - sinus congestion and pressure
  - cough due to minor throat and bronchial irritation
  - cough to help you sleep
  - runny nose and sneezing
- reduces swelling of nasal passages
- temporarily reduces fever
- promotes nasal and/or sinus drainage
- temporarily restores freer breathing through the nose

#### 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:

- blisters
- rash
- skin reddening

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
- heart disease
- thyroid disease
- high blood pressure
- glaucoma
- difficulty in urination due to enlargement of the prostate gland
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

# Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

#### When using this product

- do not exceed recommended dosage
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic beverages
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

# 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
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- 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.

## **Directions**

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#### Other information

- each caplet contains: sodium 3 mg
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- see end flap for expiration date and lot number
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

# Inactive ingredients

benzyl alcohol, black iron oxide, corn starch, crospovidone, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C yellow #6 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, polyvinyl alcohol, povidone, propylene glycol, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

# Principal display panel

#### **KIRKLAND**

Signature

COMPARE TO VICKS® DAYQUIL® & NYQUIL® VAPOCOOL® SEVERE COLD & FLU + CONGESTION

active ingredients\*

**NDC 63981-795-81** ITM. / ART. 1729556

COOL BLAST
SEVERE COLD & FLU
PLUS CONGESTION

#### Acetaminophen 325 mg,

Dextromethorphan HBr 10 mg, Guaifenesin 200 mg,

Phenylephrine HCl 5 mg

Pain Reliever • Fever Reducer • Cough

Suppressant

Expectorant • Nasal Decongestant

Relieves:

Headache, Fever, Sore Throat,

Minor Aches & Pains

Chest Congestion, Thins &

Loosens Mucus

Macal Congoction Cinuc Droccura

### Acetaminophen 325 mg,

Dextromethorphan HBr 10 mg, Doxylamine succinate 6.25 mg,

Phenylephrine HCl 5 mg

Pain Reliever • Fever Reducer • Cough Suppressant

Antihistamine • Nasal Decongestant

Relieves:

Headache, Fever, Sore Throat,

Minor Aches & Pains

Nasal Congestion,

Sinus Pressure

Sneezing, Runny Nose

ivasai Congestion, Sinus Fressure Cough Actual Size 112 DAY COATED CAPLETS

Cough Actual Size

56 NIGHT COATED CAPLETS

# 168 TOTAL CAPLETS

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

# Do Not Take Daytime and Nighttime Products at the Same Time.

\*This product is not manufactured or distributed by The Procter & Gamble Company, owner of the

registered trademark Vicks® DayQuil® and NyQuil® VapoCOOL® Severe Cold & Flu + Congestion.

50844 REV0223A79579681

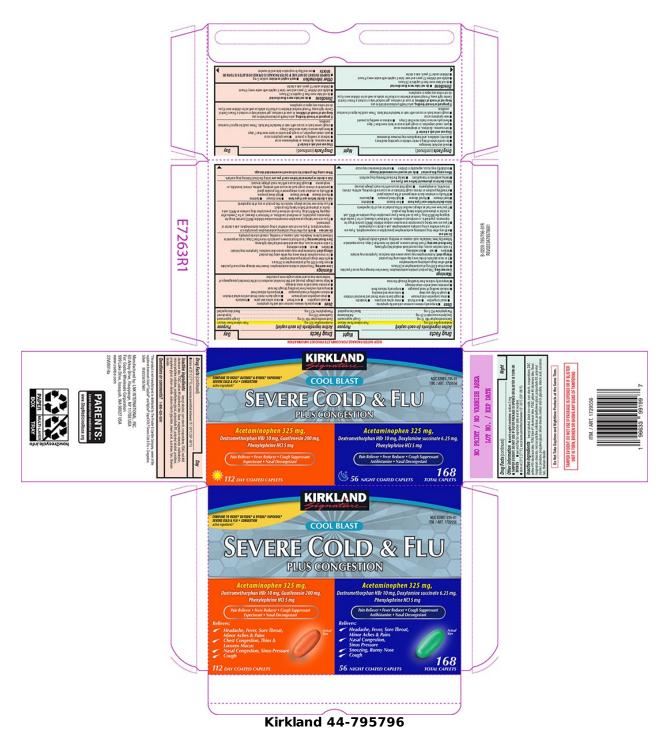
Manufactured by: LNK INTERNATIONAL, INC. 60 Arkay Drive, Hauppauge, NY 11788 USA

For: Costco Wholesale Corporation

999 Lake Drive, Issaquah, WA 98027 USA

www.costco.com

23V08014a



# SEVERE COLD AND FLU PLUS CONGESTION

acetaminophen, dextromethorphan hbr, doxylamine succinate, guaifenesin, phenylephrine hcl kit

P	Product Information				
Product Type HUMAN OTC DRUG Item Co		Item Code	(Source)	NDC:63981-795	
Pa	ackaging				
#	Item Code Package Description Marketing Start Ma		Marketing End		
				Date	Date
1	NDC:63981-795- 81	14 in 1 CARTON		06/30/2023	
,		1 in 1 BLISTER PACK; Type 0: Not a	Combination		

Quantity of Parts				
Part #	Package Quantity	Total Product Quantity		
Part 1		8		
Part 2		4		

# Part 1 of 2

# SEVERE COLD AND FLU PLUS CONGESTION DAY

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated

<b>Product Information</b>	
Item Code (Source)	NDC:63981-995
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	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients	
Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C RED NO. 40 ALUMINUM LAKE (UNII: 6T47AS764T)	
FD&C YELLOW NO. 6 ALUMINUM LAKE (UNII: GYP6Z2JR6Q)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

# **Product Characteristics**

Color	orange	Score	no score
Shape	OVAL	Size	19mm
Flavor	MENTHOL	Imprint Code	44;795
Contains			

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/30/2023	

# Part 2 of 2

# **SEVERE COLD AND FLU PLUS CONGESTION NIGHT**

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl tablet, film coated

Product Information		
Item Code (Source)	NDC:63981-996	
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	
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients			
Ingredient Name	Strength		
BENZYL ALCOHOL (UNII: LKG8494WBH)			
FERROSOFERRIC OXIDE (UNII: XM0M87F357)			
STARCH, CORN (UNII: O8232NY3SJ)			
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)			
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)			
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)			
FD&C YELLOW NO. 6 ALUMINUM LAKE (UNII: GYP6Z2JR6Q)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
POLYSORBATE 80 (UNII: 60ZP39ZG8H)			
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)			
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)			
STEARIC ACID (UNII: 4ELV7Z65AP)			

SUCRALOSE (UNII: 96K6UQ3ZD4)

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color green Score no score

Shape OVAL Size 19mm

Flavor MENTHOL Imprint Code 44;796

Contains

	Marketing Information				
l	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
	OTC Monograph Drug	M012	06/30/2023		

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/30/2023	

# Labeler - COSTCO WHOLESALE CORPORATION (103391843)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(63981-795) , pack(63981-795)

Establishment							
Name	Address	ID/FEI	<b>Business Operations</b>				
LNK International, Inc.		832867894	manufacture(63981-795)				

Establishment							
Name	Address	ID/FEI	<b>Business Operations</b>				
LNK International, Inc.		868734088	manufacture(63981-795)				

Establishment						
Name	Address	ID/FEI	<b>Business Operations</b>			
LNK International, Inc.		117025878	manufacture(63981-795)			

Revised: 4/2024 COSTCO WHOLESALE CORPORATION