# COLD AND FLU RELIEF MULTI SYMPTOM- acetaminophen, dextromethorphan hbr, phenylephrine hcl, doxylamine succinate WinCo Foods, LLC

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 Daytime (in each softgel) Acetaminophen 325 mg

Dextromethorphan HBr 10 mg Phenylephrine HCl 5 mg

# Active ingredients in Nighttime (in each softgel)

# Acetaminophen 325 mg

Dextromethorphan HBr 15 mg
Doxylamine succinate 6.25 mg

# **Purpose for Daytime**

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

# **Purpose for Nighttime**

# Pain reliever/fever reducer

Cough suppressant

**Antihistamine** 

#### Uses

- temporarily relieves common cold and flu symptoms:
  - sore throat
  - headache
  - minor aches and pains
  - fever
  - cough due to minor throat and bronchial irritation
  - nasal congestion (Daytime only)

runny nose and sneezing (Nighttime only)

## **Warnings**

**Liver warning:** These products contain 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.

# Ask a doctor before use if you have

- liver disease (Daytime-Nighttime)
- heart disease (Daytime)
- diabetes (Daytime)
- thyroid disease (Daytime)
- high blood pressure (Daytime)
- glaucoma (nighttime)
- cough that occurs with too much phlegm (mucus)
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, emphysema (Daytime)
- a breathing problem or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema (Nighttime)

# 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,

Daytime: do not use more than directed.

## **Nighttime:**

- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

# Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur (Daytime only)
- pain, cough, and nasal congestion gets worse or lasts more than 7 days (Daytime)
- pain or cough gets worse or lasts more than 3 days (Nighttime)
- 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.

**Overdose warning**: Taking more than the recommended dose can 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 )
- do not take more than 4 doses in 24 hours
- swallow whole; do not crush, chew, or dissolve

**Daytime**: adults and children 12 years and over: take 2 softgels with water every 4 hours

**Nighttime**: adults and children 12 years and over: take 2 softgels with water every 6 hours

• children under 12 years: do not use

#### Other information

- store at room temperature 15°-30°C (59°-86°F)
- avoid excessive heat

# **Inactive ingredeints for Daytime**

butylated hydroxyanisole, butylated hydroxytoluene, carminic acid\*, D&C yellow #10\*, edible white ink, FD&C red #40\*, FD&C yellow #6\*, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sodium metabisulfite\*, sorbitan, sorbitol

\*contains one or more of these ingredients

# Inactive ingredients in Nighttime

D&C yellow #10, edible white ink, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan\*, sorbitol

\*may contain this ingredient

#### Questions or comments?

Or to report an adverse event call 800-824-1706 Monday-Friday 9am-4pm MST

## **Principal Display Panel**

\*\*Compare to the Active Ingredients in VICKS® DAYQUIL® & NyQUIL® LiquiCaps®

# Multi-Symptom Cold & Flu Relief

#### **NON-DROWSY**

#### **DAYTIME**

ACETAMINOPHEN / PAIN RELIEVER - FEVER REDUCER

DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT

PHENYLEPHRINE HCI / NASAL DECONGESTANT

Relieves: Aches, Fever, Sore Throat, Cough & Nasal Congestion

#### **Nighttime**

ACETAMINOPHEN / PAIN RELIEVER - FEVER REDUCER

DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT

DOXYLAMINE SUCCINATE / ANTIHISTAMINE

Relieves: Aches, Fever, Sore Throat, Cough, Sneezing & Runny Nose.

Softgels

\*\*Liquid Filled Capsules

When using Daytime and Nighttime products, carefully read the labeling to ensure correct dosing.

# KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS

# TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

†This product is not manufactured or distributed by THE PROCTER & GAMBLE COMPANY, VICKS®, DAYQUIL®, NYQUIL® AND LiquiCap® are registered trademarks of THE PROCTER & GAMBLE COMPANY.

**DISTRIBUTED BY:** 

WINCO FOODS, LLC

BOISE, ID 83704

www.wincofoods.com

# **Product Label**

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Dung Facts (continued)

Directions

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■ do not take more than directed (see Overdose warning)

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cough comes back or occurs with rash or headache that lasts. These could be

■ pain, cough, or nasal congestion gets worse or lasts more than 7 days ■ rechess or swelling is present ■ new symptoms occur ■ fever gets worse or lasts more than 3 days Stop use and sak a doctor if m nervousness, dizziness, or steeplessness occur

When using this product, do not use more than directed.

Ask a doctor or pharmacist before use if you are taking the blood thinning

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Drug Facts (continued)

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ask a doctor or pharmacist. **m** if you are now taking a prescription monoamine oxidase inhibitor (MMOI) with any other drug containing acetaminophen (preacription or nonpreacription). If you are not sure whether a drug contains acetaminophen, acet.

a doctor prompty. 

Liver warming: This product contains actaminophen. Severe liver damage may, cours if you base: — amont bars, 400 mg of several morphen in 24 hours a with actual containing actaminophen as contained as a facility series product m 3 or more alcoholic drinks every day white using this product m 3 or more alcoholic drinks every day white using this product m 3 or more alcoholic drinks every day white using this product m 3 or more alcoholic drinks every day white using this product. Warnings

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Doxylamine succinate 6.25 mg. condy enbbusseaut Dextromethorphan HBr 15 mg. Active ingredients (in each softgel)

Nighttime Cold & Flu Softgel

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■ with other druge containing acetaminophen
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Allergy alert. Acstamnophen may cause severe skin reactions. Symptoms may cause.

Liver warming: This product contains acetaminophen. Severe liver damage may occur if you take: ■ more than 4,000 mg of acetaminophen in 24 hours

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врийпе ИСІ 5 тд Aceteminophen 325 mg.... Dextromethorphen HBr 10 mg.. Cough suppressant Active ingredients (in each softgel)

Daytime Cold & Flu Softgel

†Compare to the active ingredients in VICKS® DAYQUIL® & NYQUIL® LiquiCaps®

NON-DROWSY

Daytime

ACETAMINOPHEN/ PAIN RELIEVER - FEVER REDUCER DEXTROMETHORPHAN HBr/ **COUGH SUPPRESSANT** PHENYLEPHRINE HCI/

Relieves: Aches, Fever, Sore Throat, Cough & Nasal Congestion

ACETAMINOPHEN/ PAIN RELIEVER - FEVER REDUCER DEXTROMETHORPHAN HBr/ COUGH SUPPRESSANT DOXYLAMINE SUCCINATE/

Relieves: Aches, Fever, Sore Throat, Cough, Sneezing & Runny Nose

\*\*Liquid Filled Capsule

Nighttime

ANTIHISTAMINE

WinCo FOODS **MULTI-**Relief

48

When using Daytime and Nighttime products, carefully read the labeling to ensure correct dosing

PLD-642R FC003002 WF1471

www.wincofoods.com Comments & Questions? 800-824-1706

Lot / Exp.: DT Product of / NT Product of:



TSM mq4 - me9 ysbh7 - ysbnoM 3071-428-008

**Dung Facts** (continued)

Questions or comments? Or to report an adverse event call

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BOIZE, ID 83704 WINCO FOODS, LLC,

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

TAMPER EYDEWT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORIN, BROXZN OR SHOWS ANY SIGNS OF TAMPERING.

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**Questions or comments?** Orto report an adverse event call **800-824-1706** Monday - Friday 9am - 4pm MST

**Inactive Ingredients** D&C yallow #10, ediple white Ink. FD&C blue #1, gelabit, glyceth, polyethylone glycol, povlone, propylene glycol, punifled water, sorbibai "may contain this ingredent

Dung Facts (continued)

WinCo Foods DayTime NightTime Multi-Symptom Cold & Flu Relief

#### COLD AND FLU RELIEF MULTI SYMPTOM

acetaminophen, dextromethorphan hbr, phenylephrine hcl, doxylamine succinate kit

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:67091-309

#### **Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:67091-309- 48	1 in 1 CARTON; Type 0: Not a Combination Product	09/30/2016	12/31/2024

#### **Quantity of Parts**

Part #	Package Quantity	Total Product Quantity
Part 1	16 BLISTER PACK	16
Part 2	32 BLISTER PACK	32

# Part 1 of 2

#### COLD AND FLU RELIEF MULTI SYMPTOM NIGHTTIME

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule

#### **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	15 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients			
Ingredient Name	Strength		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
GELATIN (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
POVIDONE (UNII: FZ989GH94E)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SORBITAN (UNII: 6092ICV9RU)			
SORBITOL (UNII: 506T60A25R)			

Product Characteristics					
Color	green	Score	no score		
Shape	CAPSULE	Size	20mm		
Flavor		Imprint Code	P30;94A;215;P120		
Contains					

Pa	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1		16 in 1 CARTON			
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product			

Marketing In	Marketing Information				
Marketing Application Number or Monograph Category Citation		Marketing Start Marketing Date Date			
OTC monograph final	part341	09/30/2016	05/31/2024		

# Part 2 of 2

# COLD AND FLU RELIEF MULTI SYMPTOM NON DROWSY DAYTIME

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule

# **Product Information**

**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>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg		

Inactive Ingredients		
Ingredient Name	Strength	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)		
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
GELATIN (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6A3C0OX)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POVIDONE (UNII: FZ 989GH94E)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SORBITAN (UNII: 6092ICV9RU)		
SORBITOL (UNII: 506T60A25R)		
CARMINIC ACID (UNII: CID8Z8N95N)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
SODIUM METABISULFITE (UNII: 4VON5FNS3C)		

Product Characteristics					
Color	orange	Score	no score		
Shape	CAPSULE	Size	20mm		
Flavor		Imprint Code	P19;95A;512;P119		
Contains					

Pa	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1		32 in 1 CARTON				
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product				

Marketing Information				
	Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC monograph final	part341	09/30/2016	05/31/2024
Markatina In	formation		
Marketing Information			
Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC monograph final	part341	09/30/2016	12/31/2024

# Labeler - WinCo Foods, LLC (056098817)

Revised: 10/2023 WinCo Foods, LLC