# COLD AND FLU RELIEF DAYTIME- acetaminophen, dextromethorphan hbr, phenylephrine hci capsule, liquid filled 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 each softgel)

#### Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

## Purpose

## Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

## Uses

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

## 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.

# Ask a doctor before use if you have

- liver disease
- diabetes
- heart disease
- thyroid disease
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough as occurs with smoking, asthma, 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

- pain, cough, or nasal congestion gets worse or lasts more than 7 days
- nervousness, dizziness or sleeplessness occur
- 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
- adults and children 12 years and over: take 2 softgels with water every 4 hours
- swallow whole; do not crush, chew, or dissolve
- children under 12 years: do not use
- when using other Daytime or Nighttime products, carefully read each label to ensure correct dosing

- store between 15-30°C (59-86°F)
- avoid excessive heat

#### **Inactive ingredients**

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

\*contains one or more of these ingredients

#### Questions or comments?

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

#### **Principal Display Panel**

MULTI-SYMPTOM

Cold & Flu Relief

DayTime

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

Non-Drowsy

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

Alcohol-Free

& Antihistamine-Free

#### ACETAMINOPHEN / PAIN RELIEVER - FEVER REDUCER

#### DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT

PHENYLEPHRINE HCl / NASAL DECONGESTANT

Softgels\*\*

\*\*Liquid-Filled Capsules

<sup>†</sup>This product is not manufactured or distributed by THE PROCTER & GAMBLE COMPANY, VICKS®, DAYQUIL®, and LiquiCaps® are registered trademarks of THE PROCTER & GAMBLE COMPANY.

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

## KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

#### **DISTRIBUTED BY:**

WINCO FOODS, LLC,

BOISE, ID 83704

www.wincofoods.com

## **Product Label**



(continued) <b>store</b> (continued)	Drug Facts
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temporarily relieves common cold and flu symptoms	Acetaminophen 325 mg
minor aches and pains meadache sore throat	Dextromethorphan HBr 10 mg
assil congestion tevet cough due to minor throat and bronchial irritation	Phenylephrine HCI 5 mg.
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	Drug Facts (continued)	Drug Facts Active ingredients (in each softgel) Purposes Dextomethorphan 325 mg Dextomethorphan HBr 10 mg Dextomethorphan HBr 10 mg Dextomethorphan Br 10 mg Dextomethorpha
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Wincor MULTI-SYMPTOM Cold & Flu Relief Daytime	*Compare to the active ingredients in VICKS® DAYQUIL® Cold & Flu LiquiCaps® Non-Drowsy Relieves: Aches, Fever, Sore Throat, Cough & Nasal Congestion Alcohol-Free & Antihistamine-Free
Daytime	
ACETAMINOPHEN/ PAIN RELIEVER - FEVER REDUCER	24 Softgels**

DEXTROMETHORPHAN HBr/COUGH SUPPRESSANT

/ Exp.: fuct of:

ER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING. KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.



WinCo FOODS Multi-Symptom Cold & Flu Relief

# COLD AND FLU RELIEF DAYTIME

acetaminophen, dextromethorphan hbr, phenylephrine hci capsule, liquid filled

Product Information						
Product T ype	HUMAN OTC DRUG	Item Code (S	Source)	NDC:670	2:67091-308	
Route of Administration	ORAL					
Active Ingredient/Active Moi	ety					
Ingre	dient Name		Basis of	f Strength	Strengtl	
ACETAMINOPHEN (UNII: 36209ITL91	) (ACETAMINOPHEN - UNI	:362O9ITL9D)	ACETAMINOP	HEN	325 mg	
<b>DEXTROMETHORPHAN HYDROBRO</b> (DEXTROMETHORPHAN - UNII:7355X3)			DEXTROMETH HYDROBROMI		10 mg	
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59 TNSJ) (PHENYLEPHRINE -       PHENYLEPHRINE         UNII:1WS297W6 MV)       HYDROCHLO RIDE					5 mg	
Inactive Ingredients						
Ingredient Name					Strength	
BUTYLATED HYDRO XYANISOLE (U	NII: REK4960K2U)					
BUTYLATED HYDROXYTOLUENE (U	NII: 1P9 D0 Z171K)					
FD&C RED NO.40 (UNII: WZB9127XO	A)					
FD&C YELLOW NO.6 (UNII: H77VEI9	3A8)					
GELATIN (UNII: 2G86QN327L)						
GLYCERIN (UNII: PDC6A3C0OX)						
POLYETHYLENE GLYCOL, UNSPEC	<b>IFIED</b> (UNII: 3WJQ0SDW1A	)				
<b>POVIDONE</b> (UNII: FZ989GH94E)						
PROPYLENE GLYCOL (UNII: 6DC9Q	.67V3)					
WATER (UNII: 059QF0KO0R)						
SORBITAN (UNII: 6092ICV9RU)						
SORBITOL (UNII: 506T60A25R) CARMINIC ACID (UNII: CID8Z8N95N)						
D&C YELLOW NO. 10 (UNII: 35SW5U	503()					
SODIUM METABISULFITE (UNII: 4VO						
	10111000)					

Color	ORANGE	Score	no score			
Shape	CAPSULE	Size	20 mm	20mm		
Flavor		Imprint Code	P19;95A;512;P119	P19;95A;512;P119		
Contains						
Packaging	Packaging					
# Item Code	Package Description		Marketing Start Date	Marketing End Date		
<b>1</b> NDC:67091-308-24	2 in 1 CARTON		09/30/2016			
1	12 in 1 BLISTER PACK; Type 0: Not a Combination Product					
Marketing Information						
Marketing Catego	ry Application Numbe	r or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC MONOGRAPH FIN	AL part341		09/30/2016			

Labeler - WinCo Foods, LLC (056098817)

Revised: 10/2019

WinCo Foods, LLC