# DAYTIME NIGHTTIME COLD AND FLU- acetaminophen dextromethorphan hbr phenylephrine hci doxylaminesucinate WinCo Foods, LLC

-----

## **Drug Facts**

## Active ingredients (in each 15 mL) DAYTIME

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

## Active ingredients for (in each 30 mL) NIGHTTIME

Acetaminophen 650 mg

Dextromethorphan HBr 30 mg

Doxylamine Succinate 12.5 mg

## **Purposes for Day Time**

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

## **Purpose for Night Time**

Pain reliever/fever reducer

Cough suppressant

**Antihistamine** 

#### Uses

#### **DAYTIME**

- 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

#### **NIGHTTIME**

- temporarily relieves these common cold/flu symptoms`
  - minor aches and pains
  - headache
  - sore throat
  - runny nose and sneezing
  - fever
  - cough due to minor throat and bronchial irritation

#### Warnings

#### **DAYTIME**

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

- adult takes more than 4 doses (30 mL each) of acetaminophen in 24 hours, which is the maximum daily amount
- child takes more than 4 doses (15 mL each) in 24 hours
- taken with other drugs containing acetaminophen
- adult has 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.

#### **NIGHTTIME**

**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

#### **DAYTIME NIGHTTIME**

- 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 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

## Ask a doctor before use if you have

#### **DAYTIME**

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- a sodium-restricted diet
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough that occurs with too much phlegm (mucus)

#### **NIGHTTIME**

- liver disease
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
- trouble urinating due to enlarged prostate gland

## Ask a doctor or pharmacist before use if you are

#### **DAYTIME**

taking the blood thinning drug warfarin.

#### **NIGHTTIME**

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

## When using this product

#### **DAYTIME**

## do not exceed recommended dosage.

#### **NIGHTTIME**

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

alcohol, sedatives and tranquilizers may increase drowsiness

#### Stop use and ask a doctor if

#### DAYTIME

- nervousness, dizziness or sleeplessness occur
- pain, nasal congestion, or cough gets worse, or lasts more than 5 days(children) or 7 days (adult)
- 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.

#### **NIGHTTIME**

- pain 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.

#### **DAYTIME NIGHTTIME**

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center(1-800-222-1222) 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**

#### DAYTIME

- do not take more than directed (see Overdose warning)
- do not take more than 4 doses in any 24-hour period
- measure only with dosing cup provided. Do not use any other dosing device.
- keep dosing cup with product
- mL= milliliter

adults and children 12 years and over	30 mL every 4 hours
children 6 to under 12 years	15 mL every 4 hours
children 4 to under 6 years	ask a doctor
children under 4 years	do not use

#### **NIGHTTIME**

- do not take more than directed (see Overdose warning)
- Do not take more than 4 doses in any 24-hours period
- measure only with dosing cup provided. Do not use any other dosing device.
- mL= milliliter
- keep dosing cup with product
- adults and children 12 years and over: 30 mL every 6 hours
- children under 12 years of age: do not use
- when using other Daytime or Nighttime products, carefully read each label or ensure correct dosing

#### Other information

#### **DAYTIME**

- each 15 mL contains: sodium 12 mg
- store between 20-25°C (68-77°). Do not refrigerate

#### **NIGHTTIME**

- each 30 mL contains: potassium 5 mg
- each 30 mL contains sodium 24 mg
- store between 20-25°C (68-77°F). Do not refrigerate

## **Inactive ingredients**

## **Day Time**

citric acid, FD&C yellow #6, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol, sucralose, xanthan gum

## **Night Time**

acesulfame potassium, alcohol, anhydrous citric acid, FD&C blue #1, Fd&C red #40, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium trisodium citrate dihydrate

#### Questions or comments?

Call **1-800-824-1706** Monday-Friday 9AM-4PM MST

## **Principal Display Panel**

\*Compare to the active ingredients in VICKS® DayQuil® & NyQuil® Cold & Flu 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

#### NIGHT TIME

ACETAMINOPHEN / FEVER REDUCER

DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT

DOXYLAMINE SUCCINATE / ANTIHISTAMINE

**ALCOHOL 10%** 

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

**CHERRY FLAVOR** 

FL OZ (mL)

\*This product is not manufactured or distributed by THE PROCTER & GAMBLE COMPANY. VICKS® DayQuil® and NyQuil® are registered trademarks of THE PROCTER & GAMBLE COMPANY.

WHEN USING OTHER DAYTIME OR NIGHTTIME PRODUCTS, CAREFULLY READ EACH LABEL TO ENSURE CORRECT DOSING.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING.

**DISTRIBUTED BY:** 

WINCO FOODS, LLC, BOISE ID 83704

#### **Product Label**



## **DAYTIME NIGHTTIME COLD AND FLU**

acetaminophen dextromethorphan hbr phenylephrine hci doxylaminesucinate kit

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:67091-371

## **Packaging**

ш					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:67091-371- 12	1 in 1 KIT; Type 0: Not a Combination Product	10/14/2020	

## **Quantity of Parts**

4 44111	inty or runts		
Part #	Package Quantity	Total Product Quantity	
Part 1	1 BOTTLE	355 mL	
Part 2	1 BOTTLE	355 mL	

## Part 1 of 2

## **COLD AND FLU RELIEF MULTI SYMPTOM**

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride liquid

#### **Product Information**

Item Code (Source) NDC:67091-287

Route of Administration ORAL

#### **Active Ingredient/Active Moiety**

Active mgredient/Active molety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg in 15 mL	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL	

# **Inactive Ingredients**

mactive mgreatenes	
Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

WATER (UNII: 059QF0KO0R)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
GLYCERIN (UNII: PDC6A3C0OX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

ı	Pad	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1		355 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	10/14/2020	

## Part 2 of 2

## **COLD AND FLU RELIEF MULTI SYMPTOM NIGHTTIME**

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate liquid

<b>Product Information</b>	
Item Code (Source)	NDC:67091-260
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL

Inactive Ingredients	
Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	

ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ALCOHOL (UNII: 3K9958V90M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	CHERRY	Imprint Code		
Contains				

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1		355 mL in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M012	10/14/2020			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M012	10/14/2020			

# Labeler - WinCo Foods, LLC (056098817)

Revised: 5/2024 WinCo Foods, LLC