

**DAYTIME NIGHTTIME COLD AND FLU- acetaminophen dextromethorphan hbr  
phenylephrine hci doxylaminesuccinate  
Safeway, Inc.**

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**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°F). 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 **1-888-723-3929** Monday-Friday 7AM-6PM PST

## **Principal Display Panel**

### **DAYTIME**

**Compare to VICKS® DAYQUIL® Cold & Flu active ingredients\***

Daytime

Cold & Flu Relief

ACETAMINOPHEN 325 mg - Pain Reliever / Fever Reducer)

DEXTROMETH HBr 10 mg - Cough Suppressant

PHENHYDRAMINE HCl 5 mg - Nasal Decongestant

ORIGINAL FLAVOR

- Relieves aches, fever, sore throat, cough & nasal congestion
- For ages 6 years & over
- Non-drowsy
- Alcohol free
- Antihistamine free

when using Daytime or Nighttime products, carefully read each label to ensure correct dosing

## **NIGHT TIME**

**Compare to Vicks® NyQuil® Cold & Flu active ingredients\***

**Nighttime Cold & Flu Relief**

ACETAMINOPHEN 650 mg - Pain Reliever / Fever Reducer)

DEXTROMETHORPHAN HBr 30 mg - Cough Suppressant

DOXYLAMINE SUCCINATE 12.5 mg - Antihistamine

CHERRY FLAVOR

- Relieves Headache, fever, sore throat, minor aches & pains
- Sneezing, runny nose, cough
- For ages 12 years & over
- Nighttime relief
- Alcohol 10%

FL OZ (mL)

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

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P.O. BOX99, PLEASANTON, VA 94566-0009

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**Product Label**



SIGNATURE CARE Daytime Cold & Flu Nighttime Cold & Flu Relief

DAYTIME NIGHTTIME COLD AND FLU

acetaminophen dextromethorphan hbr phenylephrine hci doxylaminesucinate kit

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-467

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-467-24	1 in 1 KIT; Type 0: Not a Combination Product	09/30/2018	

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	355 mL
Part 2	1 BOTTLE	355 mL

Part 1 of 2

DAY TIME COLD AND FLU RELIEF NON DROWSY

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride liquid

Product Information	
Item Code (Source)	NDC:21130-866
Route of Administration	ORAL

Active Ingredient/Active Moiety		
	Ingredient Name	Basis of Strength
		325 mg

<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 15 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### 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	09/30/2018	

### Part 2 of 2

### NIGHTTIME COLD AND FLU RELIEF

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate liquid

### Product Information

<b>Item Code (Source)</b>	NDC:21130-343
<b>Route of Administration</b>	ORAL

### Active Ingredient/Active Moiety



Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>HIGH FRUCTOSE CORN SYRUP</b> (UNII: XY6UN3QB6S)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	

## Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

## 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	09/30/2018	

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	09/30/2018	

Revised: 5/2024

Safeway, Inc.