

**DAYTIME NIGHTTIME COLD AND FLU- acetaminophen dextromethorphan hbr  
phenylephrine hci doxylaminesuccinate  
The Kroger Co.**

*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 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,**

DAYTIME NIGHTTIME

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

**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 19 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, D&C yellow #10, FD&C green #3, FD&C yellow #6 flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium trisodium citrate dihydrate

## **Questions or comments?**

Call **1-800-632-6900**

## **Principal Display Panel**

COMPARE TO the active ingredient of VICKS® DAYQUIL® & VICKS® NYQUIL® COLD & FLU

\*See side panel

Cold & Flu

DayTime

Multi-Symptom Relief

Acetaminophen

Dextromethorphan HBr

Phenylephrine HCl

Pain Reliever

Fever Reducer

Cough Suppressant

Nasal Decongestant

For Ages 6 Years & Older

Antihistamine Free

Alcohol Free

Cold & Flu

### **NightTime**

Multi-Symptom Relief

Acetaminophen

Dextromethorphan HBr

Doxylamine Succinate

Pain Reliever

Fever Reducer

Cough Suppressant

Antihistamine

For ages 12 Years & Older

ALCOHOL 10%

FL OZ (mL)

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

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

DIST. BT THE KROGER CO.

CINCINNATI, OHIO 45202

www.kroger.com

Product Label



KROGER DayTime 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:30 142-667
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30 142-667-24	1 in 1 KIT; Type 0: Not a Combination Product	10/30/2020	
Quantity of Parts				
Part #	Package Quantity		Total Product Quantity	
Part 1	1 BOTTLE		355 mL	
Part 2	1 BOTTLE		355 mL	

Part 1 of 2

DAYTIME COLD AND FLU

acetaminophen dextromethorphan hbr phenylephrine hci liquid

Product Information

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 15 mL
DEXTROMETHORPHAN HYDROBROMIDE (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

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)	

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 FINAL	part341	10/30/2020	

Part 2 of 2

NIGHTTIME COLD AND FLU

acetaminophen dextromethorphan hbr doxylamine succinate liquid

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (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: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ALCOHOL (UNII: 3K9958V90M)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
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)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Packaging

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1		355 mL in 1 BOTTLE; Type 0: Not a Combination Product		

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OTC MONOGRAPH FINAL	part341	10/30/2020	

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OTC MONOGRAPH FINAL	part341	10/30/2020	

**Labeler** - The Kroger Co. (006999528)

Revised: 11/2020

The Kroger Co.