

**NITE TIME- acetaminophen, dextromethorphan hbr, doxylamine succinate solution**  
**Kroger Company**

*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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**Kroger Co. Nite Time Drug Facts**

**Active ingredients (in each 30 mL)**

Acetaminophen 650 mg

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 mg

**Purpose**

Pain reliever/fever reducer

Cough suppressant

Antihistamine

**Uses**

temporarily relieves common cold/flu symptoms:

- fever
- cough due to minor throat and bronchial irritation
- sore throat
- minor aches and pains
- runny nose and sneezing
- headache

**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.
- if you have ever had an allergic reaction to this product or any of its ingredients

## **Ask a doctor before use if you have**

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

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

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

## **When using this product**

- 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**

- 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.**

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

## Directions

- take only as directed – see Overdose warning
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL every 6 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

## Other information

- each 30 mL contains: sodium 39 mg
- store at 20-25°C (68-77°F)

## Inactive ingredients

alcohol, anhydrous citric acid, FD&C blue no. 1, FD&C red no. 40, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

## Questions or comments?

1-800-632-6900

## Package/Label Principal Display Panel

COMPARE TO the active ingredients of VICKS® NYQUIL® COLD & FLU

See side panel

NiteTime

COLD & FLU

Acetaminophen, Pain Reliever/Fever Reducer

Dextromethorphan HBr, Cough Suppressant

Doxylamine Succinate, Antihistamine

Relieves:

Aches, Fever, Sore Throat

Sneezing, Runny Nose

Cough

ALCOHOL 10%

Cherry Flavor

12 FL OZ (354mL)

**Drug Facts** (continued)

- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks

**Stop use and ask a doctor if**

- redness or swelling is present
- pain or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts.

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**Questions or comments?** 1-800-632-6900

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CINCINNATI, OHIO 45202

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www.kroger.com

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Learn about teen medicine abuse  
www.StopMedicineAbuse.org



COMPARE TO the active ingredients of  
**VICKS® NYQUIL® COLD & FLU** \*See side panel

NDC 30142-459-40



# NiteTime

## COLD & FLU

Acetaminophen, Pain Reliever/Fever Reducer  
Dextromethorphan HBr, Cough Suppressant  
Doxylamine Succinate, Antihistamine

Relieves:

- Aches, Fever, Sore Throat
- Sneezing, Runny Nose
- Cough

ALCOHOL 10%



12 FL OZ (354mL)

**Drug Facts** **DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING**

Active ingredients (in each 30 mL)	Purpose
Acetaminophen 650 mg	Pain reliever/fever reducer
Dextromethorphan HBr 30 mg	Cough suppressant
Doxylamine succinate 12.5 mg	Antihistamine

**Uses** temporarily relieves common cold/flu symptoms:

- fever
- cough due to minor throat and bronchial irritation
- sore throat
- minor aches and pains
- runny nose and sneezing
- headache

**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.

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45940 45 F5

**NITE TIME**

acetaminophen, dextromethorphan hbr, doxylamine succinate solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:30 142-459
<b>Route of Administration</b>	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
ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	

SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	

### Product Characteristics

<b>Color</b>	RED (Clear/Dark Red)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY (Menthol Aroma)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30 142-459-38	295 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/26/2011	
2	NDC:30 142-459-30	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2011	
3	NDC:30 142-459-34	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/08/2013	
4	NDC:30 142-459-40	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2013	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/26/2011	

**Labeler** - Kroger Company (006999528)

Revised: 8/2016

Kroger Company