# SUNMARK NITE TIME- acetaminophen, dextromethorphan hbr, doxylamine succinate solution Strategic Sourcing Services LLC

-----

## **McKesson 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:

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

## 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 38 mg
- store at 20-25°C (68-77°F)

## Inactive ingredients

alcohol, anhydrous citric acid, D&C yellow no. 10, FD&C green no. 3, FD&C yellow no. 6, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

### Questions?

1-800-719-9260

## Package/Label Principal Display Panel

Sunmark®

COMPARE TO VICKS® NYQUIL® COLD & FLU ACTIVE INGREDIENTS

nite time

Cold & Flu

Nighttime Relief

Pain Reliever/Fever Reducer

Cough Suppressant

**Antihistamine** 

Acetaminophen

Dextromethorphan HBr

Doxylamine Succinate

#### Relieves:

- Flu & Fever
- Runny Nose & Sneezing
- Cough & Sore throat

**ALCOHOL 10%** 

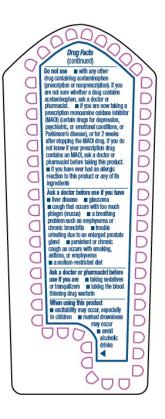
ORIGINAL FLAVOR

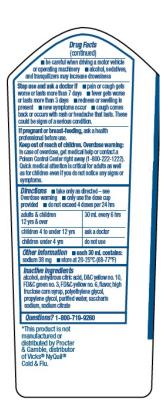
**GLUTEN FREE** 

12 FL OZ (355 mL)









#### SUNMARK NITE TIME

**Active Ingredient/Active Moiety** 

acetaminophen, dextromethorphan hbr, doxylamine succinate solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49348-061
Route of Administration	ORAL		

Ingredient Name	<b>Basis of Strength</b>	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		
ALCOHOL (UNII: 3K9958V90M)			
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)			

Product Characteristics			
Color	GREEN (clear, bright green)	Score	
Shape		Size	
Flavor	FRUIT (anise / cooling menthol aroma)	Imprint Code	
Contains			

F	Packaging			
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-061- 36	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2011	01/17/2014
2	NDC:49348-061- 49	295 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2011	01/17/2014
3	NDC:49348-061- 39	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2011	10/31/2025
4	NDC:49348-061- 37	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2011	07/31/2025

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	11/21/2011	10/31/2025

## **Labeler -** Strategic Sourcing Services LLC (116956644)

Revised: 11/2024 Strategic Sourcing Services LLC