

**NIGHTTIME- acetaminophen, dextromethorphan hbr, doxylamine succinate solution**

**Publix Super Markets Inc**

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**Publix Super Markets, Inc. Nighttime 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 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

## Package/Label Principal Display Panel

p

nitetime

ACETAMINOPHEN

DEXTROMETHORPHAN HBr

DOXYLAMINE SUCCINATE

NIGHTTIME COLD & FLU RELIEF

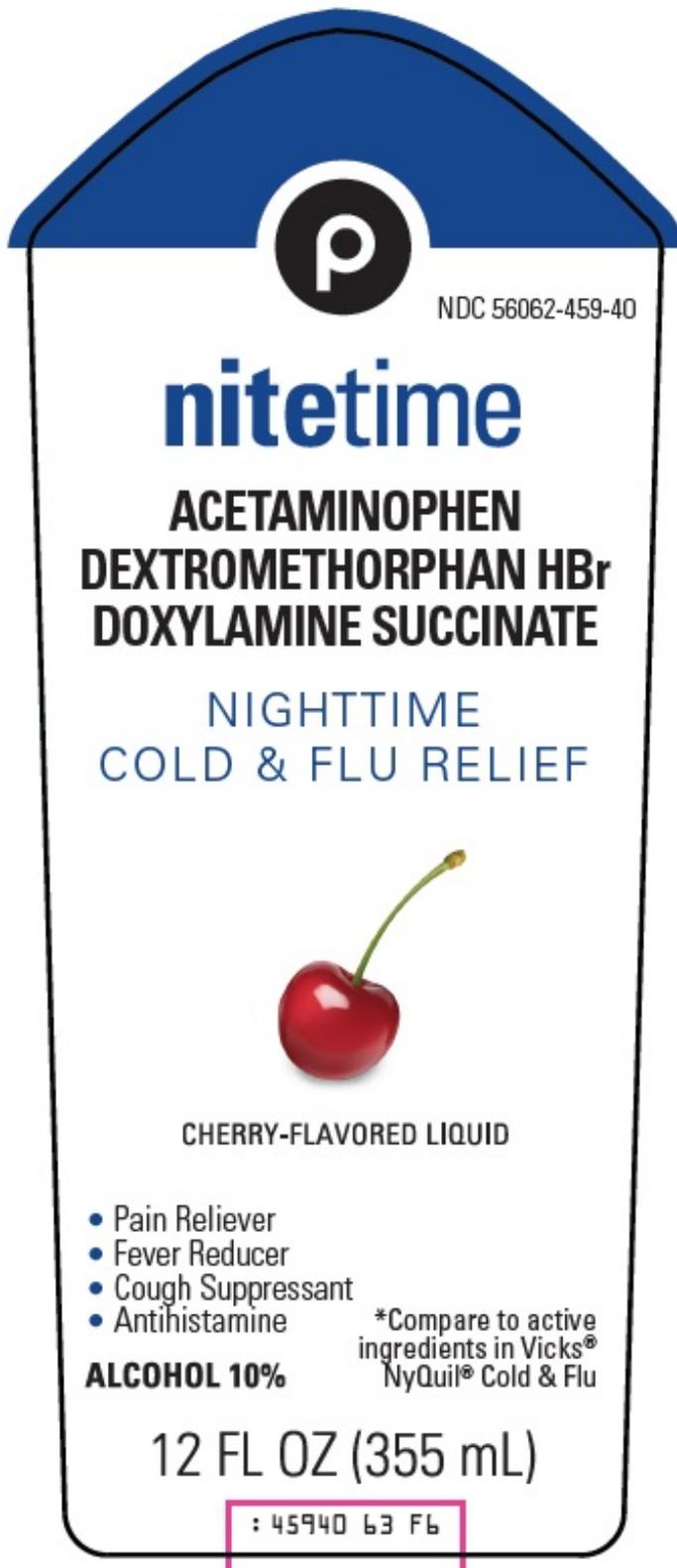
CHERRY-FLAVORED LIQUID

- Pain Reliever
- Fever Reducer
- Cough Suppressant
- Antihistamine

Compare to active ingredients in Vicks® NyQuil® Cold & Flu

ALCOHOL 10%

12 FL OZ (355 mL)



The image shows a product label for Nitetime. At the top is a blue arched cap with a white circle containing a black 'P' logo. Below the cap, the NDC number 'NDC 56062-459-40' is printed. The brand name 'nitetime' is in a large, bold, blue font. Below it, the active ingredients 'ACETAMINOPHEN', 'DEXTROMETHORPHAN HBr', and 'DOXYLAMINE SUCCINATE' are listed in bold black text. The product description 'NIGHTTIME COLD & FLU RELIEF' is in a smaller blue font. A realistic image of a red cherry with a green stem is centered below the text. Underneath the cherry, it says 'CHERRY-FLAVORED LIQUID'. A bulleted list of benefits includes 'Pain Reliever', 'Fever Reducer', 'Cough Suppressant', and 'Antihistamine'. A comparison note states '\*Compare to active ingredients in Vicks® NyQuil® Cold & Flu'. The alcohol content 'ALCOHOL 10%' is listed. The volume '12 FL OZ (355 mL)' is printed in a large black font. At the bottom, a pink rectangular box contains the number ': 45940 63 F6'.

NDC 56062-459-40

**nitetime**

**ACETAMINOPHEN  
DEXTROMETHORPHAN HBr  
DOXYLAMINE SUCCINATE**

NIGHTTIME  
COLD & FLU RELIEF



CHERRY-FLAVORED LIQUID

- Pain Reliever
- Fever Reducer
- Cough Suppressant
- Antihistamine

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

**ALCOHOL 10%**

12 FL OZ (355 mL)

: 45940 63 F6

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**PUBLIX GUARANTEE:**  
COMPLETE SATISFACTION  
OR YOUR MONEY BACK

**Publix.**

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

## PARENTS:

Learn about teen medicine abuse

[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

### Drug Facts

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:

- 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.



**PEEL BACK AT  
CORNER FOR MORE  
INFORMATION**

: 45940 63 81



**Drug Facts**  
(continued)

**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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**ADHESIVE AREA**  
**NO COATING • NO VARNISH • NO TYPE**

**Drug Facts**  
(continued)

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

**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

\*This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks® NyQuil® Cold & Flu.

ADHESIVE AREA  
NO COATING • NO VARNISH • NO TYPE

## NIGHTTIME

acetaminophen, dextromethorphan hbr, doxylamine succinate solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:56062-459
<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>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<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>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (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:56062-459-40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2014	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	11/07/2011	

**Labeler** - Publix Super Markets Inc (006922009)

