

# **ALL NITE- acetaminophen, dextromethorphan hbr, doxylamine succinate solution**

## **Major Pharmaceuticals**

*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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## **Major Pharmaceuticals All-Nite Cold & Flu Nighttime Relief 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
- use dose cup
- 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 or comments?**

1-800-616-2471

**Package/Label Principal Display Panel**

All-Nite

COLD & FLU NIGHTTIME RELIEF

ACETAMINOPHEN, DEXTROMETHORPHAN HBr, DOXYLAMINE SUCCINATE

PAIN RELIEVER, FEVER REDUCER, COUGH SUPPRESSANT, ANTIHISTAMINE

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

8 FL. OZ. (237 mL)

10% ALCOHOL

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

\*Major® All-Nite is not manufactured or distributed by The Procter & Gamble Company, owner of the registered trademarks Vicks® NyQuil®.

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**MAJOR®**  
**PHARMACEUTICALS**  
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M-05 REV. 01/16  
Re-Order No. 700414



**Gluten Free**

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**MAJOR®**

NDC 0904-6465-09

**All-Nite**

**COLD & FLU  
NIGHTTIME RELIEF**

**ACETAMINOPHEN,  
DEXTROMETHORPHAN HBr,  
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COMPARE TO the active ingredients of  
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**8 FL. OZ. (237 mL) 10% ALCOHOL**

**Drug Facts**

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

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  
 ■ minor aches and pains ■ headache ■ fever  
 ■ runny nose and sneezing ■ sore throat

**Warnings**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take  
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 ■ with other drugs containing acetaminophen  
 ■ 3 or more alcoholic drinks every day while using this product

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 ■ 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.

PEEL BACK AT CORNER FOR MORE INFORMATION →

**Drug Facts (continued)**

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**Drug Facts (continued)**

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**Directions**

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  - use dose cup ■ 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
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**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 or comments?** 1-800-616-2471

**ALL NITE**

acetaminophen, dextromethorphan hbr, doxylamine succinate solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0904-6465
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
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<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: V9B19B5Y12) (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>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C GREEN NO. 3</b> (UNII: 3P3ONR6O1S)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>HIGH FRUCTOSE CORN SYRUP</b> (UNII: XY6UN3QB6S)	
<b>POLYETHYLENE GLYCOL</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6465-09	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/19/2012	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	11/19/2012	

**Labeler** - Major Pharmaceuticals (191427277)