

## **COLD AND FLU NIGHTTIME- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate liquid**

### **Best Choice (Valu Merchandisers 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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### **Drug Facts**

#### **Active ingredients (in each 15 mL)**

**Acetaminophen 500 mg**

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.5 mg

#### **Purposes**

##### **Pain reliever/fever reducer**

Cough suppressant

Antihistamine

#### **Uses**

temporarily relieves these common cold/flu symptoms:

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

#### **Warnings**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4 doses (120 mL) in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**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**

- to make a child sleepy
- 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.
- with any other drug containing acetaminophen (prescription or non-prescription). If you are not sure

whether a drug contains acetaminophen, ask a doctor or pharmacist

- if you are allergic to acetaminophen or any of the inactive ingredients in this product

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

- liver disease
- glaucoma
- breathing problems
- chronic bronchitis
- a sodium-restricted diet
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma or emphysema or if cough is accompanied by excessive phlegm (mucus)

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

- sedatives or tranquilizers
- the blood thinning drug warfarin

**When using this product**

- **do not use more than directed (see overdose warning)**
- 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**

- redness or swelling is present
- new symptoms occur
- fever gets worse or lasts more than 3 days
- pain or cough gets worse or lasts more than 7 days
- 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:** 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) immediately. 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 recommended (see overdose warning)
- do not exceed 4 doses per 24 hours
- use dosage cup provided
- mL= milliliter

age	dose
adults & children 12 years and over	30 mL every 6 hrs

children 4 to 11 yrs	do not use unless directed by a doctor
children under 4 yrs	do not use

- **When using other Day Time or Night Time products, carefully read each label to ensure correct dosing**

#### **Other information**

- **each 15 mL contains:** sodium 18 mg
- store at room temperature.

#### **Inactive ingredients**

alcohol, 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, sodium citrate

#### **Questions or comments?**

Call **1-877-753-3935 Monday-Friday 9AM-5PM EST**

#### **Principal Display Panel**

COMPARE TO THE ACTIVE INGREDIENTS OF VICKS® NYQUIL®\*

#### **Nighttime Cold & Flu**

#### **MULTI-SYMPTOM RELIEF**

ACETAMINOPHEN PAIN RELIEVER / FEVER REDUCER

DEXTROMETHORPHAN COUGH SUPPRESSANT

DOXYLAMINE SUCCINATE ANTIHISTAMINE

ORIGINAL FLAVOR

FL OZ (mL)

10 % ALCOHOL

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**Failure to follow these warnings could result in serious consequences.**

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

PROUDLY DISTRIBUTED BY:

VALU MERCHANDISERS, CO.

5000 KANSAS AVE

KANSAS CITY, KS 66106

[www.bestchoicebrand.com](http://www.bestchoicebrand.com)

#### **Product Label**

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**PARENTS:**  
Learn about teen medicine abuse  
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5000 KANSAS AVE  
KANSAS CITY, KS 66106



COMPARE TO THE ACTIVE INGREDIENTS OF VICKS® NYQUIL®\*

**Best Choice®**

# Nighttime Cold & Flu

**MULTI-SYMPPTOM RELIEF**  
**ACETAMINOPHEN**.....PAIN RELIEVER/ FEVER REDUCER  
**DEXTROMETHORPHAN HBr**.....COUGH SUPPRESSANT  
**DOXYLAMINE SUCCINATE**.....ANTIHISTAMINE

**ORIGINAL FLAVOR**  
**10 FL OZ (296 mL) 10% ALCOHOL**

Failure to follow these warnings could result in serious consequences.

**Drug Facts**

Active ingredients (in each 15 mL)	Purposes
Acetaminophen 500 mg.....	Pain reliever/fever reducer
Dextromethorphan HBr 15 mg.....	Cough suppressant
Doxylamine succinate 6.25 mg.....	Antihistamine

**Uses** temporarily relieves these common cold/flu symptoms:  
 ■ minor aches and pains ■ headache ■ sore throat ■ fever  
 ■ runny nose and sneezing ■ itchy nose or throat ■ coughs  
 ■ cough due to minor throat and bronchial irritation

**Warnings**  
**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take: ■ more than 4 doses (120 mL) in 24 hours, which is the maximum daily amount ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks everyday while using this product  
**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** ■ to make a child sleepy ■ 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. ■ with any other drug containing acetaminophen (prescription or non-prescription). If you are not sure whether a drug ▶

**Drug Facts (continued under label) PEEL HERE** →

**Drug Facts (continued)**

contains acetaminophen, ask a doctor or pharmacist. ■ if you are allergic to acetaminophen or any of the inactive ingredients in this product

**Ask a doctor before use if you have** ■ liver disease ■ glaucoma  
 ■ breathing problems ■ chronic bronchitis ■ a sodium-restricted diet  
 ■ trouble urinating due to an enlarged prostate gland ■ persistent or chronic cough such as occurs with smoking, asthma or emphysema or if cough is accompanied by excessive phlegm (mucus)

**Ask a doctor or pharmacist before use if you are taking**  
 ■ sedatives or tranquilizers ■ the blood thinning drug warfarin

**When using this product** ■ do not use more than directed (see overdose warning) ■ 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** ■ redness or swelling is present  
 ■ new symptoms occur ■ fever gets worse or lasts more than 3 days  
 ■ pain or cough gets worse or lasts more than 7 days  
 ■ 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:** 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) immediately. Quick medical ▶

**Drug Facts (continued)**

attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions** ■ take only as recommended (see overdose warning)  
 ■ do not exceed 4 doses per 24 hours ■ use dosage cup provided  
 ■ mL = milliliter

age	dose
adults and children 12 years and over	30 mL every 6 hours
children 4 to 11 years	do not use unless directed by a doctor
children under 4 years	do not use

■ When using Day Time and Night Time products, carefully read each label to ensure correct dosing

**Other information** ■ each 15 mL contains: sodium 18 mg  
 ■ store at room temperature

**Inactive ingredients** alcohol, 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, sodium citrate

**Questions or comments?**  
 Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

## Best Choice NightTime Cold & Flu Original Flavor

### COLD AND FLU NIGHTTIME

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate liquid

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63941-346
<b>Route of Administration</b>	ORAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg in 15 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg in 15 mL
DOXYLAMINE SUCCINATE (UNII: V9B19B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg in 15 mL

**Inactive Ingredients**

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63941-346-06	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/31/2016	
2	NDC:63941-346-10	296 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/31/2016	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	03/31/2016	

**Labeler** - Best Choice (Valu Merchandisers Company) (868703513)

Revised: 5/2016

Best Choice (Valu Merchandisers Company)