

**NIGHTTIME COLD AND FLU RELIEF- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled  
Walgreen 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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**Walgreen Co. Nighttime Cold & Flu Relief Drug Facts**

**Active ingredients (in each liquid cap)**

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

**Purpose**

Pain reliever/fever reducer

Cough suppressant

Antihistamine

**Uses**

temporarily relieves common cold and flu symptoms:

- sore throat
- headache
- minor aches and pains
- fever
- runny nose and sneezing
- 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 8 liquid caps 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**

- 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.

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

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

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

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

**When using this product**

- **do not exceed recommended dosage**
- excitability may occur, especially in children
- avoid alcoholic drinks
- marked drowsiness may occur
- alcohol, sedatives and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

**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:** Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions**

- **do not take more than directed (see overdose warning)**
- do not take more than 8 liquid caps in 24 hours
- adults and children 12 years and over: take 2 liquid caps with water every 6 hours
- children under 12 years: do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage.

**Other information**

- store at controlled room temperature 15°C to 30°C (59°F to 86°F)
- see end flap for expiration date and lot number

**Inactive ingredients**

D&C yellow #10\*, edible ink, FD&C blue #1\*, FD&C green #3\*, gelatin, glycerin, polyethylene

glycol, povidone, propylene glycol, purified water, sorbitol, \* contains one or more of these ingredients

**Questions or comments?**

1-800-706-5575

**Principal Display Panel**

MULTI-SYMPTOM NIGHTTIME

Cold & Flu Relief

Acetaminophen / Aches / Fever / Sore throat

Dextromethorphan HBr / Cough

Doxylamine Succinate / Sneezing / Runny Nose

Compare to Vicks<sup>®</sup> NyQuil<sup>®</sup> active ingredients<sup>‡</sup>



# NIGHTTIME COLD AND FLU RELIEF

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0363-1005
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

## Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONES (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	

## Product Characteristics

<b>Color</b>	GREEN	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	35A
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-1005-01	2 in 1 CARTON		
1		8 in 1 BLISTER PACK		
2	NDC:0363-1005-02	2 in 1 CARTON		
2		12 in 1 BLISTER PACK		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/09/2012	

**Labeler** - Walgreen Company (008965063)

Revised: 10/2012

Walgreen Company