

**NIGHT TIME COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled**

**Retail Business Services, LLC**

*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.*

-----

**Night Time Cold & Flu**

Drug Facts

**Active ingredient (in each softgel)**

**Acetaminophen 325 mg**

Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine HCl 5 mg

**Purposes**

**Pain reliever/fever reducer**

Cough suppressant

Antihistamine

Nasal decongestant

**Uses**

- temporarily relieves these common cold and flu symptoms:
- cough
- nasal congestion
- minor aches and pains
- sore throat
- headache
- runny nose
- sneezing
- temporarily reduces fever
- controls cough to help you get to sleep

**Warnings**

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

- more than 4 doses in 24 hrs, which is the maximum daily amount for this product
- 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.

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

- liver disease
- heart disease
- diabetes
- high blood pressure
- thyroid disease
- glaucoma
- trouble urinating due to an enlarged prostate gland
- breathing problems such as emphysema or chronic bronchitis
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, 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 use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

### **Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, 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 12 softgels in any 24-hour period
- adults and children 12 years of age and older: take 2 softgels every 4 hours
- children under 12 years of age: do not use

**Other information**

- store between 15-30°C (59-86°F)
- avoid excessive heat

**Inactive ingredient**

D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, and white edible ink

**Questions or Comments?**

Call toll free: **1-866-322-2439**

**PRINCIPAL DISPLAY PANEL**

CareOne Nighttime Cold & Flu 16ct

compare to Mucinex Fast-Max Night Time Cold & Flu active ingredients

NDC 72476-998-14

Maximum Strength\*

# Night Time Cold & Flu

THIS PRODUCT IS PACKAGED IN  
A CHILD RESISTANT AND TAMPER  
EVIDENT PACKAGE. USE ONLY IF  
BLISTERS ARE INTACT

NDC 72476-998-14

\*\*Compare to the active ingredients in Mucinex®  
Fast-Max® Night Time Cold & Flu.

Maximum Strength\*

# Night Time Cold & Flu

**Acetaminophen** – Pain Reliever/Fever Reducer  
**Dextromethorphan HBr** – Cough Suppressant  
**Doxylamine succinate** – Antihistamine  
**Phenylephrine HCl** – Nasal Decongestant

- Relieves Aches, Fever and Sore Throat
- Relieves Runny Nose & Sneezing
- Relieves Nasal Congestion
- Controls Cough



**12-24 SOFTGELS**

For Ages 12+

Maximum Strength\*  
Night Time  
Cold & Flu

\*Per 4-hour dose  
Do not take more than  
a total of 12 softgels  
in a 24-hour period



**PARENTS:**

Learn about teen medicine abuse

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

\*\*This product is not manufactured or distributed by Reckitt Benckiser, owner of the registered trademarks Mucinex® Fast-Max® Night Time Cold & Flu.

Distributed By:  
COMPANY NAME  
ADDRESS  
Made in China  
CMB11-01

<b>Drug Facts</b>		<b>Drug Facts (continued)</b>	
<b>Active ingredients (in each softgel)</b>		<b>Purposes</b>	
Acetaminophen 325 mg.....Pain reliever/fever reducer		■ persistent or chronic cough such as occurs with smoking, asthma, or emphysema	
Dextromethorphan HBr 10 mg.....Cough suppressant		Ask a doctor or pharmacist before use if you are	
Doxylamine succinate 6.25 mg.....Antihistamine		■ taking the blood thinning drug warfarin	
Phenylephrine HCl 5 mg.....Nasal decongestant		■ taking sedatives or tranquilizers	
<b>Uses</b>		<b>When using this product</b>	
■ temporarily relieves these common cold and flu symptoms:		■ do not use more than directed	
■ cough ■ nasal congestion		■ excitability may occur, especially in children	
■ minor aches and pains ■ sore throat		■ marked drowsiness may occur	
■ headache ■ runny nose ■ sneezing		■ alcohol, sedatives, and tranquilizers may increase drowsiness	
■ temporarily reduces fever		■ avoid alcoholic drinks	
■ controls cough to help you get to sleep		■ be careful when driving a motor vehicle or operating machinery	
<b>Warnings</b>		<b>Stop use and ask a doctor if</b>	
Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:		■ nervousness, dizziness, or sleeplessness occur	
■ more than 12 softgels in 24 hours, which is the maximum daily amount		■ pain, nasal congestion, or cough gets worse or lasts more than 7 days	
■ with other drugs containing acetaminophen		■ fever gets worse or lasts more than 3 days	
■ 3 or more alcoholic drinks daily while using this product		■ redness or swelling is present	
<b>Allergy Alert:</b> Acetaminophen may cause severe skin reactions. Symptoms may include:		■ new symptoms occur	
■ skin reddening ■ blisters ■ rash		■ cough comes back, or occurs with rash or headache that lasts. These could be signs of a serious condition.	
If a skin reaction occurs, stop use and seek medical help right away.		<b>If pregnant or breast-feeding, ask a health professional before use.</b>	
<b>Sore throat warning:</b> 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.		<b>Keep out of reach of children.</b>	
<b>Do not use</b>		<b>Overdose warning:</b> 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.	
■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.		<b>Directions</b>	
■ 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.		■ do not take more than directed (see Overdose warning)	
<b>Ask a doctor before use if you have</b>		■ do not take more than 12 softgels in any 24-hour period	
■ liver disease ■ heart disease ■ diabetes		■ adults and children 12 years of age and older: take 2 softgels every 4 hours	
■ high blood pressure ■ thyroid disease ■ glaucoma		■ children under 12 years of age: do not use	
■ trouble urinating due to an enlarged prostate gland		<b>Other information</b>	
■ breathing problems such as emphysema or chronic bronchitis		■ store between 15-30°C (59-86°F)	
■ cough that occurs with too much phlegm (mucus)		■ avoid excessive heat	
		<b>Inactive ingredients</b>	
		D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, and white edible ink	
		<b>Questions or comments?</b>	
		Call toll free: 1-XXX-XXX-XXXX	

## NIGHT TIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72476-998
<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	10 mg

<b>DOXYLAMINE SUCCINATE</b> (UNII: V9B19B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	

### Product Characteristics

<b>Color</b>	green (Clear)	<b>Score</b>	no score
<b>Shape</b>	capsule (Oblong)	<b>Size</b>	21mm
<b>Flavor</b>		<b>Imprint Code</b>	PC22
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72476-998-14	2 in 1 CARTON	03/18/2019	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/18/2019	

**Labeler** - Retail Business Services, LLC (967989935)

### Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(72476-998) , analysis(72476-998)