

**DAY TIME AND NIGHT TIME COLD AND FLU FORMULA- acetaminophen,  
dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride  
PuraCap Pharmaceutical 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.*

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**DAY TIME and NIGHT TIME COLD & FLU FORMULA**

**Drug Facts**

**Active ingredients for Day Time (in each softgel)**

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

**Purposes**

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

**Active ingredients for Nite Time (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 symptoms due to a cold or flu:
- minor aches and pains
- headache
- nasal and sinus congestion
- cough
- sore throat
- runny nose and sneezing (Nighttime only)

- temporarily reduces fever

## **Warnings**

### **Liver warning**

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

- more than 10 softgels in 24 hours, 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

### **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.

**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.

**Do not use to sedate children (Nighttime only).**

### **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
- in children under 12 years of age

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

- liver disease
- heart disease
- high blood pressure
- diabetes
- thyroid disease
- cough with excessive phlegm (mucus)
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- glaucoma (Nighttime only)
- a breathing problem such as emphysema or chronic bronchitis (Nighttime only)

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

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers (Nighttime only)

### **When using this product**

- **do not exceed recommended dosage**

**In addition when using NiteTime:**

- may cause marked drowsiness
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

**Stop use and ask a doctor if**

- pain, cough, or nasal congestion 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.

- nervousness, dizziness, or sleeplessness occurs

**If pregnant or breast-feeding**, ask a health professional before use.

**Keep out of reach of children.**

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****DayTime & NiteTime**

- do not take more than the recommended dose
- adults and children 12 years and over: take 2 softgels with water every 4 hours. Do not exceed 10 softgels in 24 hours or as directed by a doctor.
- children under 12 years: do not use

**Other information**

- store at room temperature. Avoid excessive heat

**DayTime**

FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol special, and white edible ink

**NiteTime**

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

**Questions or comments?**

Call toll free: **1-800-833-6278**

**Principal Display Panel**

DAY TIME and NIGHT TIME COLD & FLU FORMULA

NDC 51013-158-08

\*Compare to the active ingredients in Alka-Seltzer PLUS® Day and Night Cold and Flu Formula



## DAY TIME AND NIGHT TIME COLD AND FLU FORMULA

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride kit

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:510 13-158
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:510 13-158-08	1 in 1 CARTON; Type 0: Not a Combination Product	07/20/2016	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
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<b>Part 1</b>	1 BLISTER PACK	10
<b>Part 2</b>	1 BLISTER PACK	10

## Part 1 of 2

### DAY TIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled

#### Product Information

**Route of Administration** 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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

#### Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

#### Product Characteristics

<b>Color</b>	orange (clear)	<b>Score</b>	no score
<b>Shape</b>	capsule (oblong)	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	PC9
<b>Contains</b>			

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		10 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	07/20/2016	

## Part 2 of 2

### NIGHT TIME COLD AND FLU

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

## Product Information

Route of Administration 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
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

## Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

## Product Characteristics

Color	green (clear)	Score	no score
Shape	capsule (oblong)	Size	20mm
Flavor		Imprint Code	PC22
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	07/20/2016		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	07/20/2016		

**Labeler** - PuraCap Pharmaceutical LLC (962106329)

**Establishment**

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd		421293287	manufacture(510 13-158) , analysis(510 13-158)

Revised: 1/2020

PuraCap Pharmaceutical LLC