

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

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**Day Time Cold & Flu Formula and Night Time Cold & Flu Formula**

**Active ingredients (in each softgel)**

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

Acetaminophen 325 mg  
Dextromethorphan hydrobromide 10 mg  
Phenylephrine hydrochloride 5 mg

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

Acetaminophen 325 mg  
Dextromethorphan hydrobromide 10 mg  
Doxylamine succinate 6.25 mg  
Phenylephrine hydrochloride 5 mg

**Purposes**

**DG Day Time Cold & Flu Formula**

Pain reliever/fever reducer  
Cough suppressant  
Nasal decongestant

**DG Night Time Cold & Flu Formula**

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 (Night Time only)
- temporarily reduces fever

## **Warnings**

### **Liver warning**

These products contain 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(Night Time 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
- thyroid disease
- diabetes
- 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 (Night Time only)
- a breathing problem such as emphysema or chronic bronchitis (Night Time only)

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

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

### **When using this product**

- **do not exceed recommended dosage**

### **In addition when using Night Time**

- 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**

- 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.

### **Inactive ingredients (Day Time)**

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

### **Inactive ingredients (Night Time)**

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: **1-888-309-9030**

**Principal Display Panel - Carton Label**

DG Day and Night Cold and Flu Formula

NDC 51013-168-08

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



# DG DAY TIME COLD AND FLU FORMULA 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:51013-168

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51013-168-08	1 in 1 CARTON; Type 0: Not a Combination Product	06/15/2016	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BLISTER PACK	12
Part 2	1 BLISTER PACK	8

## Part 1 of 2

### DG DAY TIME COLD AND FLU FORMULA

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled

## Product Information

Route of Administration	ORAL
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## 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	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: 3WJQ05DW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

## Product Characteristics

Color	orange (clear)	Score	no score
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<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		12 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 Drug	M012	06/15/2016	

### Part 2 of 2

#### DG NIGHT TIME COLD AND FLU FORMULA

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
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5 mg
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 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, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	

**POVIDONE** (UNII: FZ989GH94E)

**PROPYLENE GLYCOL** (UNII: 6DC9Q167V3)

**WATER** (UNII: 059QF0KO0R)

**SORBITOL** (UNII: 506T60A25R)

### Product Characteristics

<b>Color</b>	green (clear)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (oblong)	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	PC22
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
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 Drug	M012	06/15/2016	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/15/2016	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd		421293287	manufacture(51013-168)

Revised: 11/2024

PuraCap Pharmaceutical LLC