

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

**Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.**

*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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**NIGHTTIME COLD AND FLU capsule, liquid filled**

**Active ingredients (in each capsule)**

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/flu symptoms:

- cough due to minor throat & bronchial irritation
- sore throat
- headache
- minor aches/pains
- fever
- runny nose & sneezing

**Warnings**

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

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

**Sore throat warning** If sore throat is severe, lasts more than 2 days, occurs with or is followed by fever, headache, rash, nausea, or vomiting, see 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.
- To make a child sleep

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

- liver disease
- glaucoma
- 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
- trouble urinating due to enlarged prostate gland

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

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

**When using this product**

- **do not use more than directed**
- 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**

- 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 directed can cause serious health problems. 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 children even if you do not notice any signs or symptoms.

**Directions**

- take only as directed - see **Overdose warning**
- do not exceed 4 doses per 24 hours

adults and children 12 years of age and over	take 2 softgels with water every 6 hours
children 4 to 12 years of age	ask a doctor
children under 4 years of age	<b>do not use</b>

**When using other Nighttime or Daytime products, carefully read each label to ensure correct dosing.**

**Other information**

- store at room temperature 15°-30°C (59°-86°F)

**Inactive ingredients**

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

Manufactured by:

Humanwell PuraCap Pharmaceutical (Wuhan) Ltd.

Wuhan, Hubei 430206,

China

**PRINCIPAL DISPLAY PANEL - Shipping Label**

NIGHTTIME COLD AND FLU CAPSULES

Quantity : 4000 Capsules

NDC. No : 53345-026-01

**IMPORTANT:**

1. Inspect immediately upon receipt.
2. This is a bulk shipment, intended for further processing only.
3. Protect from heat, humidity, and light. Do not refrigerate.
4. Store at 15-30°C (59-86°F)

**CAUTION : "FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING"**

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**Humanwell PuraCap Pharmaceutical (Wuhan) Ltd.**

No. 99, 2nd Shendun Road, East Lake New Technology Development District,  
Wuhan, Hubei 430206, P. R. China

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**NDC No.: 53345-026-01**

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Product:

**Nighttime Cold and Flu Capsules**

Each softgel contains: Acetaminophen 325 mg/Dextromethorphan HBr  
15 mg/Doxylamine Succinate 6.25 mg

**CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING**

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Product Code:

43-01660

Quantity:

4000 Capsules

Lot Number:

xxxxxxx

Manufacturing Date:

xx/yyyy

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Box No.:

**IMPORTANT:**

1. Inspect immediately upon receipt.
2. This is a bulk shipment, intended for further processing only.
3. Protect from heat, humidity, and light. Do not refrigerate.
4. Store at 15-30°C (59-86°F)

**MADE IN CHINA**

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**REV-00**

**07/2014**

**NIGHTTIME COLD AND FLU**

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

**Product Information**

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:53345-026

**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	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: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	

**Product Characteristics**

Color	green	Score	no score
Shape	CAPSULE (oblong)	Size	21mm
Flavor		Imprint Code	660
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53345-026-01	1 in 1 BOX	08/11/2014	
1		4000 in 1 BAG; 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	08/11/2014	

**Labeler** - Humanwell PuraCap Pharmaceutical (Wuhan), Ltd. (421293287)**Establishment**

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.		421293287	MANUFACTURE(53345-026) , ANALYSIS(53345-026)