

NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled
Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.

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
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

Sore throat warning: If sore throat is severe, persists 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.

- To make a child sleep

Ask a doctor before use if you have

- liver disease
- glaucoma
- cough with excessive phlegm(mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema
- difficulty in urinating due to an 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 exceed the recommended dosage**
- do not use for more than 7 days
- excitability may occur especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and Ask a doctor if

- you get nervous, dizzy, or sleepless
- swelling or redness is present
- symptoms do not get better or are accompanied by a fever that lasts more than 3 days or if new symptoms occur
- cough lasts more than 7 days (adults) or 5 days (children), recurs or is accompanied by fever, rash, or persistent headache.

These may 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) could cause serious health problems.In case of overdose, get medical help or contact a Poison Control Center right away. Prompt 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	Swallow 2 softgels with water every 6 hours
Children 4 to 12 years of age	ask a doctor
children under 4 years of age	do not use

If taking NIGHTTIME and DAYTIME softgels carefully read each label to insure correct dosing.

Other information

- store at room temperature 15°-30°C (59°-86°F) and avoid excessive heat
- this product does not contain phenylpropanolamine (PPA)

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 : 53345-006-01

IMPORTANT:

Inspect immediately upon receipt.
This is a bulk shipment intended for further processing only.
Protect from heat, humidity, and light. Do not refrigerate.

CAUTION : "FOR FURTHER MANUFACTURING, PROCESSING OR REPACKING"

Humanwell PuraCap Pharmaceutical (Wuhan) Ltd.

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

NDC No.: 53345-006-01

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

Product Code:

40-00010

Quantity:

4000 Capsules

Lot No.:

0000000

Manufacturing Date:

00/0000

Box No.:

X

MADE IN CHINA

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.

REV-01
01/2013

Humanwell PuraCap Pharmaceuticals (Wuhan) Co.,Ltd

NDC #: 53345-006-01

PLD Item: BK000516



BK000516



NIGHTTIME NO PSE PE SOFTGEL PUR BULK

LOT # XXXXXXX

MFG DATE: MM/DD/YY



XXXXXXXX



MM/DD/YY

QTY/Case: 4,000 capsules

CAUTION:
FOR FUTURE MANUFACTURING,
PROCESSING OR REPACKAGING

Made in China

IMPORTANT:

1. Protect from heat, humidity, and light.
2. Store at 15-30°C (59-86°F) and avoid excessive heat above 40°C (104°F).

COMMENTS:
PO#:

REV-00
08/2019

NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53345-006
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: V9B19B5Y12) (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 (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	green	Score	no score
Shape	CAPSULE (oblong)	Size	21mm
Flavor		Imprint Code	PC10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53345-006-01	1 in 1 BOX	04/15/2013	
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 Drug	M012	04/15/2013	

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

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.		421293287	manufacture(53345-006)

Revised: 11/2024

Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.