

NIGHTTIME SINUS- acetaminophen, doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled

Humanwell PuraCap Pharmaceutical (Wuhan) Co., 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.

NightTime Sinus Capsule, liquid filled

Active ingredients (in each softgel)

Acetaminophen 325 mg

Doxylamine succinate 6.25 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever

Antihistamine

Nasal decongestant

Uses

temporarily relieves nasal and sinus symptoms:

- sinus pain
- headache
- nasal and sinus congestion
- runny nose and 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

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

- 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
- heart disease
- thyroid disease
- diabetes
- high blood pressure
- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- 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 & tranquilizers may increase drowsiness

Stop use and ask a doctor if

- redness or swelling is present
- you get nervous, dizzy or sleepless
- fever gets worse or lasts more than 3 days
- new symptoms occur
- symptoms do not get better within 7 days or are accompanied by a fever

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 and 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 hrs

adults and children 12 years of age and over	take 2 softgels with water every 4 hrs
Children 4 to	

under 12 years of age	ask a doctor
children under 4 years of age	do not use

- **when using other Daytime or Nighttime products, carefully read each label to insure correct dosing**

Other information

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

Inactive ingredients

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

Manufactured by:

Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.

Wuhan, Hubei

430206, China

PRINCIPAL DISPLAY PANEL - Shipping Label

NightTime Sinus Capsules

Quantity : 4000 Capsules

NDC. No : 53345-031-01

IMPORTANT:

Inspect immediate 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 REPACKAGING"

Humanwell PuraCap Pharmaceutical (Wuhan) Ltd.

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

NDC No.: 53345-031-01

Product:

Nighttime Sinus Capsules

Each softgel contains: Acetaminophen 325 mg/ Phenylephrine HCl 5 mg/
Doxylamine Succinate 6.25 mg

CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product Code:

43-01665

Quantity:

4000 Capsules

Lot Number:

XXXXXXX

Manufacturing Date:

xx /yyyy

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

**REV-00
10/2014**

NIGHTTIME SINUS

acetaminophen, doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:53345-031

Route of Administration

ORAL

Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	325 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	
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: 059QF0K00R)				
SORBITOL (UNII: 506T60A25R)				
Product Characteristics				
Color	blue	Score	no score	
Shape	CAPSULE (oblong)	Size	21mm	
Flavor		Imprint Code	665	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53345-031-01	1 in 1 BOX	02/26/2015	
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	02/26/2015		

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

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	MANUFACTURE(53345-031) , ANALYSIS(53345-031)

Revised: 11/2019

Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.