NIGHTTIME SINUS RELIEF- acetaminophen, doxylamine succinate, phenylephrine hydrochloride 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.

NightTime Sinus Relief capsule, liquid filled

Active ingredients (in each capsule)

Acetaminophen 325 mg

Doxylamine succinate 6.25 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever

Antihistamine

Nasal decongestant

Uses

temporarily relieves nasal & sinus symptoms:

- sinus pain
- headache
- nasal & sinus congestion
- 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

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 & for 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 & children 12 yrs & over	2 softgels with water every 4 hrs
Children 4 to under 12 yrs	ask a doctor
children under 4 yrs	**do not use**

- **when taking NIGHTTIME and DAYTIME 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, titanium dioxide

Manufactured by:
Humanwell PuraCap Pharmaceutical (Wuhan) Ltd.
Wuhan, Hubei
430206, China

PRINCIPAL DISPLAY PANEL - Shipping Label

NightTime Sinus Relief Capsules

Quantity : 4000 Capsules
NDC. No : 53345-013-01

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 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.: 53345-013-01

Product:

NightTime Sinus Relief 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: **40-00016**	Quantity: **4000 Capsules**
Lot No.: **0000000**	Manufacturing Date: **00/0000**
Box No.: **X**	**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.
MADE IN CHINA	

REV – 00
04/2013

NIGHTTIME SINUS RELIEF

acetaminophen, doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53345-013
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: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	blue	**Score**	no score
Shape	CAPSULE (oblong)	**Size**	21mm
Flavor		**Imprint Code**	PC13
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:53345-013-01	1 in 1 BOX	06/15/2013	
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 final	part341	06/15/2013	

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

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.		421293287	MANUFACTURE(53345-013) , ANALYSIS(53345-013)

Revised: 11/2019 Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.