

**NIGHTTIME SINUS RELIEF- acetaminophen, doxylamine succinate,
phenylephrine hydrochloride capsule, liquid filled
Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.**

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 11 yrs | 1 softgel 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 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.: 53345-013-01

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: V9B19B5Y12) (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: PDC6A3C00X) | |
| 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 Drug | M012 | 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) |

Revised: 11/2024

Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.