

**DAYTIME SINUS- acetaminophen, phenylephrine hydrochloride capsule, liquid filled**

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

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**DayTime Sinus Capsules, liquid filled**

**Active ingredients (in each capsule)**

Acetaminophen 325 mg

Phenylephrine HCl 5 mg

**Purpose**

Pain reliever

Nasal decongestant

**Uses**

temporarily relieves sinus symptoms:

- sinus pain
- headache
- nasal and sinus congestion

**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

**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.

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

- liver disease
- heart disease
- thyroid disease
- diabetes
- high blood pressure
- trouble urinating due to enlarged prostate gland

**Ask a doctor or pharmacist before use if you are** taking the blood thinning drug warfarin.

**When using this product, do not use more than directed.**

**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. 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	take 2 softgels with water every 4 hours
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 Yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol special and white edible ink

Manufactured by:

Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.

Wuhan, Hubei

430206, China

### **PRINCIPAL DISPLAY PANEL - Shipping Label**

DayTime Sinus Capsules

Quantity : 4000 Capsules

NDC. No : 53345-030-01

**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"**

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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.: 53345-030-01**

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Product:

**Daytime Sinus Capsules**

Each softgel contains: Acetaminophen 325 mg/Phenylephrine HCl 5 mg

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

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Product Code:

43-01663

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  
10/2014**

**DAYTIME SINUS**

acetaminophen, phenylephrine hydrochloride capsule, liquid filled

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53345-030
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

## Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

## Product Characteristics

Color	orange	Score	no score
Shape	CAPSULE (oblong)	Size	21mm
Flavor		Imprint Code	663
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53345-030-01	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 Drug	M012	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(53345-030)

Revised: 11/2024

Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.