

**DAYTIME SINUS RELIEF- acetaminophen, 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.*

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**DayTime Sinus Relief capsule, 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 & 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
- 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.

**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. 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 hours

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	<b>do not use</b>

- **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 Yellow #6, 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**

DayTime Sinus Relief Capsules

Quantity : 4000 Capsules

NDC. No : 53345-012-01

**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, 2<sup>nd</sup> Shendun Road, East Lake New Technology Development District,  
Wuhan, Hubei 430206, P. R. China

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**NDC No.: 53345-012-01**

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Product:

### DayTime Sinus Relief Capsules

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

CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product Code: <b>40-00015</b>	Quantity: <b>4000 Capsules</b>
Lot No.: <b>0000000</b>	Manufacturing Date: <b>00/0000</b>
Box No.: <b>X</b>	<b>IMPORTANT:</b> 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.
<b>MADE IN CHINA</b>	

REV - 00  
04/2013

### DAYTIME SINUS RELIEF

acetaminophen, phenylephrine hydrochloride capsule, liquid filled

#### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53345-012
Route of Administration	ORAL		

<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	325 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)		PHENYLEPHRINE HYDROCHLORIDE	5 mg	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
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: 059QF0K00R)				
SORBITOL (UNII: 506T60A25R)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
<b>Product Characteristics</b>				
<b>Color</b>	orange	<b>Score</b>	no score	
<b>Shape</b>	CAPSULE (oblong)	<b>Size</b>	21mm	
<b>Flavor</b>		<b>Imprint Code</b>	PC12	
<b>Contains</b>				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53345-012-01	1 in 1 BOX	06/15/2013	
1		4000 in 1 BAG; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
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(53345-012) , ANALYSIS(53345-012)

Revised: 11/2019

Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.