DAYTIME SINUS RELIEF- acetaminophen, phenylephrine hydrochloride capsule, liquid filled Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.

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

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

• 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"

Humanwell PuraCap Pharmaceutical (Wuhan) Ltd.

No. 99, 2^{no} Shendun Road, East Lake New Technology Development District, Wuhan, Hubei 430206, P. R. China

NDC No.: 53345-012-01

Product:

DayTime Sinus Relief Capsules

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

CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product Code: 40-00015 Lot No.: 0000000		Quantity: 4000 Capsules		
		00/0000		
		Box No.: X		diately up on receipt.
MADE IN CHINA	 This is a bulk shipment intended for further processing only. Protect from heat, humidity, and light. Do not refrigerate. 			

REV-00 04/2013

DAYTIME SINUS RELIEF					
acetaminophen, phenylephrir	ne hydrochloride capsu	ule, liquid fillec	l		
Product Information					
Product Type	HUMAN OTC DRUG	ltem Code (Source)		NDC:53345-012	
Route of Administration	ORAL				
Active Ingredient/Active Moiety					
Ingredient Name			Basis of Strength		Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)			ACETAMINOPHEN		325 mg
		PHENYLEPHRINE HYDROCHLORIDE		5 mg	

Inactive Ingredients

FD&C YELLOW NO. 6 (UNII: H77VEI93A8) GELATIN (UNII: 2G86QN327L) GLYCERIN (UNII: PDC6A3C00X) POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDWLA) POLYEDAUE (UNII: 57000CU04E)	
GLYCERIN (UNII: PDC6A3C0OX) POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ 989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	Score	no score
Shape	CAPSULE (oblong)	Size	21mm
Flavor		Imprint Code	PC12
Contains			

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:53345-012- 01	1 in 1 BOX	06/15/2013	
1		4000 in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	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(53345-012)	

Revised: 11/2024

Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.