

**DAY TIME SINUS RELIEF- acetaminophen, phenylephrine hydrochloride capsule, liquid filled
PuraCap Pharmaceutical LLC**

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.

Day Time Sinus Relief

Drug Facts

Active ingredients (in each softgel)

Acetaminophen 325 mg

Phenylephrine HCl 5 mg

Purposes

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 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. 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 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

Questions or comments?

Call toll free: **1-855-215-8180**

PRINCIPAL DISPLAY PANEL

Day Time Sinus Relief 16 SOFTGELS

NDC 51013-185-14

*Compare to the active ingredients in Vicks® DayQuil® Sinex® LiquiCaps®



DAY TIME SINUS RELIEF

acetaminophen, phenylephrine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51013-185
Route of Administration	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: 059QF0K00R)				
SORBITOL (UNII: 506T60A25R)				
Product Characteristics				
Color	orange (clear)	Score	no score	
Shape	capsule (oblong)	Size	19mm	
Flavor		Imprint Code	PC12	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:510 13-185-14	2 in 1 CARTON	07/14/2016	
1		8 in 1 BLISTER PACK; 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	07/14/2016		

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(510 13-185) , analysis(510 13-185)

Revised: 1/2020

PuraCap Pharmaceutical LLC