

**DAYTIME SINUS RELIEF AND NIGHTTIME SINUS RELIEF- acetaminophen, doxylamine succinate, phenylephrine hydrochloride**  
**Chain Drug Marketing Association Inc.**

*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 and Nighttime Sinus Relief**

**Active ingredients for Nighttime Sinus (in each softgel)**

Acetaminophen 325 mg

Doxylamine succinate 6.25 mg

Phenylephrine HCl 5 mg

**Active ingredients for Daytime Sinus (in each softgel)**

Acetaminophen 325 mg

Phenylephrine hydrochloride 5 mg

**Purposes**

**Nighttime Sinus Relief**

Pain reliever/Fever reducer

Antihistamine

Nasal decongestant

**Purposes**

**Daytime Sinus Relief**

Pain reliever/Fever reducer

Nasal decongestant

**Uses**

- temporarily relieves symptoms due to the common cold
  - minor aches and pains
  - headache
  - fever
  - runny nose and sneezing (Nighttime only)
  - nasal congestion
  - sinus congestion & pressure
- temporarily relieves symptoms due to hay fever or other upper respiratory allergies
  - minor aches and pains
  - headache
  - runny nose and sneezing (Nighttime only)
  - itching of the nose or throat, and itchy, watery eyes (Nighttime only)
  - nasal congestion

- sinus congestion & pressure

## **Warnings**

### **Liver warning**

These products contain acetaminophen. Severe liver damage may occur if you take

- more than 10 softgels in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day 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 (Nighttime only)

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

- liver disease
- heart disease
- thyroid disease
- diabetes
- high blood pressure
- glaucoma (Nighttime only)
- a breathing problem such as emphysema or chronic bronchitis (Nighttime only)
- trouble urinating due to enlarged prostate gland

### **Ask a doctor or pharmacist before use if you are**

- taking sedatives or tranquilizers (Nighttime only)
- taking the blood thinning drug warfarin

### **When using this product**

- **do not use more than directed, in addition when using Nighttime Sinus and Congestion:**
- 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**

- pain or nasal congestion gets worse or last more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- you get nervous, dizzy or sleepless

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children.**

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
- do not exceed 4 doses per 24 hours

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<b>Age</b>	<b>Daytime Sinus</b>	<b>Nighttime Sinus</b>
adults and children 12 years and over	2 softgels with water every 4 hours	2 softgels with water every 4 hours
children 4 to under 12 years	ask a doctor	ask a doctor
children under 4 years	do not use	do not use

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### Other information

- store at room temperature 15°-30°C (59°-86°F) and avoid excessive heat

### Inactive ingredients

**Nighttime Sinus:** FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol special, white edible ink

**Daytime Sinus:** FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol special, white edible ink

### Questions or comments?

Call 248-449-9300

### Principal Display Panel

CDMA Daytime Sinus Relief and Nighttime Sinus Relief 48 SOFTGELS

NDC 63868-464-48

Compare to the active ingredients in Vicks® QlearQuil™ Daytime Sinus & Congestion and Nighttime Sinus & Congestion\*

**THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT**

**Drug Facts**

**Active Ingredients for Nighttime Sinus (in each softgel)** **Purpose**  
 Acetaminophen 325 mg.....Pain reliever/Fever reducer  
 Doxylamine succinate 6.25 mg.....Antihistamine  
 Phenylephrine HCl 5 mg.....Nasal decongestant

**Active Ingredients for Daytime Sinus (in each softgel)** **Purpose**  
 Acetaminophen 325 mg.....Pain reliever/Fever reducer  
 Phenylephrine HCl 5 mg.....Nasal decongestant

**Uses**

- temporarily relieves symptoms due to the common cold
- minor aches and pains ■ headache ■ fever
- runny nose and sneezing (Nighttime Sinus only) ■ nasal congestion
- sinus congestion and pressure
- temporarily relieves symptoms due to hay fever or other upper respiratory allergies
- minor aches and pains ■ headache ■ runny nose and sneezing (Nighttime Sinus only)
- itching of the nose or throat, and itchy, watery eyes (Nighttime Sinus only)
- nasal congestion ■ sinus congestion and pressure

**Warnings**

- Liver warning** These products contain 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 these products
- 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 these products.
- to make a child sleep (Nighttime Sinus only)

**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 ■ glaucoma (Nighttime Sinus only)
- a breathing problem such as emphysema or chronic bronchitis (Nighttime Sinus only)

**Ask a doctor or pharmacist before use if you are**

- taking sedatives or tranquilizers (Nighttime Sinus only)
- taking the blood thinning drug warfarin



Compare to the active ingredients in Vicks® QlearQuil™ Nighttime and Vicks® QlearQuil™ Daytime Sinus & Congestion\*

NDC 63868-464-48

**Non-Drowsy DayTime Sinus Relief**

**ACETAMINOPHEN 325 mg**  
 Sinus Headache & Pain  
**PHENYLEPHRINE HCl 5 mg**  
 Sinus Pressure & Congestion  
 Pain Reliever  
 Nasal Decongestant  
 Alcohol Free  
 Antihistamine Free

**48 Softgels Total**



Actual Size

**32 Daytime Softgels**

**NightTime Sinus Relief**

**ACETAMINOPHEN 325 mg**  
 Sinus Headache & Pain  
**DOXYLAMINE SUCCINATE 6.25 mg**  
 Runny Nose  
**PHENYLEPHRINE HCl 5 mg**  
 Sinus Pressure & Congestion  
 Pain Reliever  
 Antihistamine  
 Nasal Decongestant  
 Alcohol Free



Actual Size

**16 Nighttime Softgels**



## DAYTIME SINUS RELIEF AND NIGHTTIME SINUS RELIEF

acetaminophen, doxylamine succinate, phenylephrine hydrochloride kit

### Product Information

**Product Type** HUMAN OTC DRUG **Item Code (Source)** NDC:63868-464

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-464-48	1 in 1 CARTON; Type 0: Not a Combination Product	04/12/2017	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	4 BLISTER PACK	32
Part 2	2 BLISTER PACK	16

### Part 1 of 2

#### DAYTIME SINUS RELIEF

acetaminophen, phenylephrine hydrochloride capsule, liquid filled

## Product Information

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: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

## Product Characteristics

Color	orange (clear)	Score	no score
Shape	capsule (oblong)	Size	20mm
Flavor		Imprint Code	PC12
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4 in 1 CARTON		
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	04/12/2017	

## Part 2 of 2

### NIGHTTIME SINUS RELIEF

acetaminophen, doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled

## Product Information

### 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
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

## Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
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	blue (clear)	Score	no score
Shape	capsule (oblong)	Size	20mm
Flavor		Imprint Code	PC13
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 in 1 CARTON		
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	04/12/2017	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/12/2017	

**Labeler** - Chain Drug Marketing Association Inc. (011920774)

## **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd		421293287	manufacture(63868-464) , analysis(63868-464)

Revised: 12/2019

Chain Drug Marketing Association Inc.