

**NITETIME SINUS RELIEF- acetaminophen, doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled**  
**TOP CARE (Topco Associates 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.*

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**Drug Facts**

**Active ingredients (in each softgel)**

**Acetaminophen 325 mg**

Doxylamine Succinate 6.25 mg

Phenylephrine HCl 5 mg

**Purpose**

**Pain reliever**

Antihistamine

Nasal decongestant

**Uses**

- temporarily relieves nasal and sinus symptoms:
  - sinus pain
  - headache
  - nasal and sinus congestion
  - runny nose and sneezing

**Warnings**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Do not use**

- to make a child sleep
- 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
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

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

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

**When using this product**

- **do not exceed recommended dosage**
- 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, and tranquilizers may increase drowsiness

**Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- pain or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

These could be signs of a serious condition.

**If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of reach of children.**

**Overdose warning:** Taking more than the recommended dose could cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions**

- **do not take more than directed (see Overdose warning)**
- do not take more than 4 doses in 24 hours
- adults and children 12 years and over: take 2 softgels with water every 4 hours
- swallow whole; do not crush, chew, or dissolve
- children under 12 years: do not use
- **when using other Daytime or Nitetime products, carefully read each label to insure correct dosing**

**Other information**

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

**Inactive ingredients**

edible white ink, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol,

purified water, sorbitan, sorbitol

**Questions or comments?**

Call toll free **1-888-423-0139**

**Principal Display Panel**

MULTI-SYMPTOM

**Nitetime Sinus Relief**

PAIN RELIEVER, ANTIHISTAMINE AND NASAL DECONGESTANT

- Aches: **ACETAMINOPHEN**
- Sneezing/Runny Nose: Doxylamine succinate
- Nasal Congestion: Phenylephrine HCl

COMPARE TO VICKS® NYQUIL® SINEX® LIQUICAPS® active ingredients\*

SOFTGELS

\*This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® NyQuil® Sinex® LiquiCaps®.

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ELK GROVE VILLAGE, IL 60007

topcare@topco.com

Product of Canada

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.**

**TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.**

**Product Label**

**Top Care**

**TopCare**

MULTI-SYMP TOM

**Nitetime Sinus Relief**  
PAIN RELIEVER, ANTIHISTAMINE AND NASAL DECONGESTANT

MULTI-SYMP TOM

# Nitetime Sinus Relief

PAIN RELIEVER, ANTIHISTAMINE AND NASAL DECONGESTANT

- Aches: **ACETAMINOPHEN**
- Sneezing/Runny Nose: **Doxylamine succinate**
- Nasal Congestion: **Phenylephrine HCl**



24 SOFTGELS



COMPARE TO VICKS® NYQUIL® SINEX® LIQUICAPS® active ingredients\*



Supports Children's Miracle Network Hospitals  
Helping Local Kids

NDC 8800-101-24

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topcare@topco.com  
Product of Canada



This TOP CARE® product is laboratory tested to ensure its highest quality. Your total satisfaction is guaranteed.

PLD-C  
FC001565

†A portion of the proceeds from this purchase will support the Children's Miracle Network Hospitals.



Lot No.:  
Exp. Date:

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.  
TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

<p><b>Drug Facts (continued)</b></p> <p>■ sinus pain ■ headache ■ nasal and sinus congestion</p> <p>■ runny nose and sneezing</p> <p><b>Warnings</b></p> <p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:</p> <ul style="list-style-type: none"> <li>■ more than 4,000 mg of acetaminophen in 24 hours</li> </ul>	<p><b>Drug Facts (continued)</b></p> <p>■ redness or swelling is present ■ new symptoms occur</p> <p>These could be signs of a serious condition.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p><b>Keep out of reach of children.</b></p> <p>Overdose warning: Taking more than the recommended dose can cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.</p> <p><b>Directions</b></p> <p>■ do not take more than directed (see Overdose warning)</p> <p>■ do not take more than 4 doses in 24 hours</p> <p>■ adults and children 12 years and over: take 2 softgels with water every 4 hours</p> <p>■ swallow whole; do not crush, chew, or dissolve</p> <p>■ children under 12 years: do not use</p> <p>■ when using other Daytime or Nighttime products, carefully read each label to insure correct dosing</p>
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<p><b>Drug Facts (continued)</b></p> <p>■ with other drugs containing acetaminophen</p> <p>■ 3 or more alcoholic drinks every day while using this product</p> <p>Do not use</p> <ul style="list-style-type: none"> <li>■ to make a child sleep</li> <li>■ with any other drug containing acetaminophen (prescription or nonprescription), if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</li> <li>■ 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, ask a doctor or pharmacist before taking this product.</li> </ul> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>■ liver disease ■ heart disease</li> <li>■ thyroid disease ■ diabetes</li> <li>■ high blood pressure ■ glaucoma</li> <li>■ trouble urinating due to an enlarged prostate gland</li> <li>■ a breathing problem such as emphysema or chronic bronchitis</li> </ul> <p><b>Ask a doctor or pharmacist before use if you are</b></p> <ul style="list-style-type: none"> <li>■ taking the blood thinning drug warfarin</li> <li>■ taking sedatives or tranquilizers</li> </ul> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>■ do not exceed recommended dosage</li> <li>■ excitability may occur, especially in children</li> <li>■ marked drowsiness may occur</li> <li>■ avoid alcoholic drinks</li> <li>■ be careful when driving a motor vehicle or operating machinery</li> <li>■ alcohol, sedatives, and tranquilizers may increase drowsiness</li> </ul> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>■ nervousness, dizziness, or sleeplessness occur</li> <li>■ pain or nasal congestion gets worse or lasts more than 7 days</li> <li>■ fever gets worse or lasts more than 3 days</li> </ul>	<p><b>Drug Facts (continued)</b></p> <p><b>Active ingredients (in each softgel)</b></p> <p>Acetaminophen 325 mg Pain reliever</p> <p>Doxylamine succinate 6.25 mg Antihistamine</p> <p>Phenylephrine HCl 5 mg Nasal decongestant</p> <p><b>Uses</b></p> <p>■ temporarily relieves nasal and sinus symptoms.</p>
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**Other information**

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

**Inactive ingredients** edible white ink, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol

**Questions or comments?**  
Call toll free 1-888-423-0139

This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® Nyquil® Sinex® Liquicaps®.

# NITETIME SINUS RELIEF

acetaminophen, doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-101
<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
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 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: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

## Product Characteristics

<b>Color</b>	BLUE	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	47A
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-101-24	2 in 1 CARTON	09/01/2012	12/31/2020
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:36800-101-16	2 in 1 CARTON	09/01/2012	12/31/2020
2		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	09/01/2012	12/31/2020

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**Labeler** - TOP CARE (Topco Associates LLC) (006935977)

**Registrant** - P & L Development, LLC (800014821)

Revised: 8/2019

TOP CARE (Topco Associates LLC)