NITETIME SINUS- acetaminophen, doxylamine succinate and phenylephrine hydrochloride capsule, liquid filled MEIJER, 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.

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 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 children even if you do not notice any signs or symptoms.

Directions

- do not use 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 and NiteTime products, carefully read each label to ensure 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 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to Vicks® NyQuil® Sinex® LiquiCaps® active ingredients†

Liquid Capsules

NiteTime Sinus

Pain Reliever, Antihistamine, Nasal Decongestant

Acetaminophen, Doxylamine succinate, Phenylephrine HCl

Multi-Symptom Relief

Relief of: sinus headache & pain, runny nose, sinus pressure & congestion

Softgels

DIST. BY MEIJER DISTRIBUTION, INC.

2929 WALKER AVE NW

GRAND RAPIDS, MI 49544

www.meijer.com

Product of Canada

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

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.

Package Label

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

CSII 1-811-123-3332 Woudsh-Fridsy 9AM-5PM EST Questions or comments?

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NDC 41250-101-24

Compare to Vicks® NyQuil® Sinex® LiquiCaps®

active ingredients[†]

meijer

Liquid Capsules

NiteTima

Pain Reliever, Antihistamine, Nasal Decongestant Acetaminophen, Doxylamine Succinate, Phenylephrine HCl

Multi-Symptom Relief

Relief of: sinus headache & pain, runny nose, sinus pressure & congestion



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Date:

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DIST. BY MEIJER DISTRIBUTION, INC. 2929 WALKER AVE NW GRAND RAPIDS, MI 49544 www.meijer.com



Product of Canada

PLD-B FC001495



Meijer NiteTime Sinus Multi-Symptom Relief Softgels

NITETIME SINUS

acetaminophen, doxylamine succinate and phenylephrine hydrochloride capsule, liquid filled

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:41250-101

Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg	
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1W5297W6MV)	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)	
SORBITAN (UNII: 6092ICV9RU)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color	blue	Score	no score
Shape	CAPSULE	Size	20mm
Flavor		Imprint Code	47A
Contains			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:41250- 101-24	2 in 1 CARTON	09/14/2010	12/31/2024		
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product				

Marketing Information			
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
rt341	09/14/2010	12/31/2024	
Α	application Number or Monograph Citation	application Number or Monograph Marketing Start Citation Date	

Labeler - MEIJER, INC. (006959555)

Revised: 1/2023 MEIJER, INC.