

NON-DROWSY SINUS DAYTIME- acetaminophen and phenylephrine hcl tablet, film coated

GREAT LAKES WHOLESALE, MARKETING, & SALES, 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.

Healthcare 44-466C-SC-Delisted

Active ingredients (in each caplet)

Acetaminophen 325 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Nasal decongestant

Uses

- temporarily relieves these symptoms associated with hay fever or other respiratory allergies, and the common cold:
 - minor aches and pains
 - headache
 - nasal congestion
 - sinus congestion and pressure
- helps decongest sinus openings and passages
- promotes sinus drainage
- helps clear nasal passages
- temporarily reduces fever

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

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- blisters
- rash
- skin reddening

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.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- liver disease
- difficulty in urination due to enlargement of the prostate gland
- heart disease
- diabetes
- thyroid disease
- high blood pressure

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin.

When using this product

do not exceed recommended dosage.

Stop use and ask a doctor if

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

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.

In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt 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**
- adults and children 12 years and over

- take 2 caplets every 4 hours
- swallow whole - do not crush, chew, or dissolve
- do not take more than 10 caplets in 24 hours
- children under 12 years: ask a doctor

Other information

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°C-30°C (59°F-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, crospovidone, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C red #40 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

Questions or comments?

Call 1-800-426-9391

Principal Display Panel

HEALTHCARE™

NDC 64092-845-24

****Compare to the active ingredients in Tylenol®
SINUS + HEADACHE***

**Non-Drowsy Sinus
Daytime CAPLETS**

***Acetaminophen 325 mg -
Pain reliever/Fever reducer***

***Phenylephrine HCl 5 mg -
Nasal decongestant***

Relieves:

- *Headache Pain*
- *Sinus Pressure*
- *Nasal Congestion*

Pseudoephedrine FREE

**24 COOL CAPLETS
with Cool Blast Flavor**

**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS
OPENED OR IF BLISTER UNIT IS TORN, BROKEN**

OR SHOWS ANY SIGNS OF TAMPERING

*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Tylenol® SINUS + HEADACHE. 50844 REV0721H46608

Distributed by: Great Lakes Wholesale & Marketing L.L.C.
3729 Patterson Ave., S.E.
Grand Rapids, MI 49512 www.glwholesale.com

HEALTH CARE GUARANTEE

If you are not completely satisfied with this product, regardless of reason, return your unused portion to Great Lakes Wholesale for a full refund

No print/No varnish
Lot & Exp date

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Drug Facts
KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Active ingredients
(in each caplet)
Acetaminophen 325 mg.....Pain reliever/fever reducer
Phenylephrine HCl 5 mg.....Nasal decongestant

Purpose

Uses
Temporarily relieves these symptoms associated with hay fever or other respiratory allergies, and the common cold:
■ minor aches and pains
■ headache
■ nasal congestion
■ sinus congestion and pressure

Drug Facts (continued)

HEALTHCARE™

NDC 64092-845-24

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Non-Drowsy Sinus Daytime CAPLETS

Acetaminophen 325 mg - Pain reliever/Fever reducer

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Relieves:

- Headache Pain
- Sinus Pressure
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Pseudoephedrine FREE

Actual Size

24 COOL CAPLETS with Cool Blast Flavor

Drug Facts (continued)

Inactive ingredients
corn starch, croscopolone, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C red #40 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone.

Drug Facts (continued)
silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

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■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
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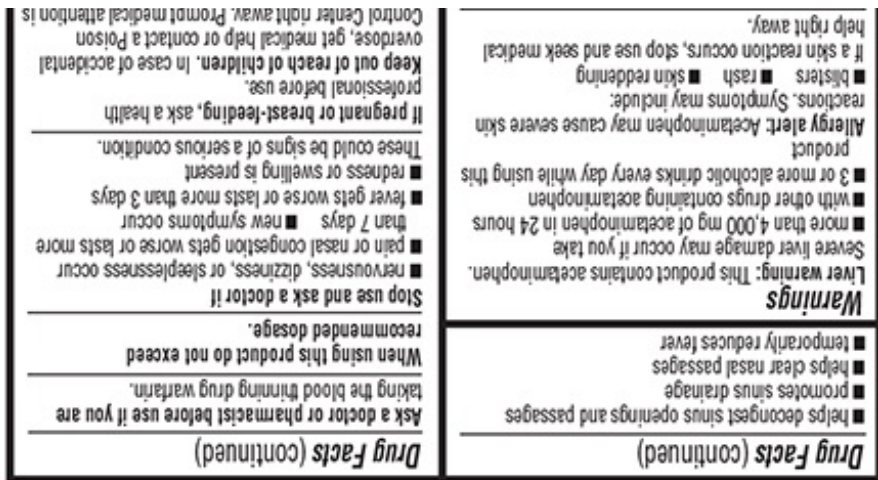
TAMPER EVIDENT: DO NOT USE IF OUTER OR BLENDED IS OPENED OR BLENDED IS TORN OR BROKEN
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see end flap for expiration date and lot number

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3729 Patterson Ave., S.E.
Grand Rapids, MI 49512 www.glw.com

B-0616-466C-08-SC
REV0721H46608



HealthCare 44-466C REV0721H

NON-DROWSY SINUS DAYTIME

acetaminophen and phenylephrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64092-845
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:1VS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	17mm
Flavor	MENTHOL	Imprint Code	44;466
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64092-845-24	2 in 1 CARTON	07/26/2005	10/21/2024
1		12 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	07/26/2005	10/21/2024

Labeler - GREAT LAKES WHOLESAL, MARKETING, & SALES, INC. (361925498)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(64092-845) , pack(64092-845)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(64092-845)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(64092-845)

Revised: 9/2023

GREAT LAKES WHOLESAL, MARKETING, & SALES, INC.