

SINUS CONGESTION AND PAIN RELIEF NON-DROWSY- acetaminophen, phenylephrine hcl tablet, film coated

WinCo Foods, 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.

Winco 44-466C

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 in 24 hours, which is the maximum daily amount
- 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

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

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
- 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.

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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°-30°C (59°-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, silica gel, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

Questions?

Call **800-824-1706** Monday - Friday 9am - 4pm MST

Principal Display Panel

WinCo®
FOODS

NON-DROWSY
**Sinus Congestion
& Pain Relief**

Daytime

*Compare to the active ingredients in **TYLENOL® Sinus + Headache**

Relieves: Sinus Headache,
Sinus Pressure
& Nasal Congestion

Cool Blast Flavor

**ACETAMINOPHEN/
PAIN RELIEVER - FEVER REDUCER**

PHENYLEPHRINE HCl/NASAL DECONGESTANT

24
Caplets

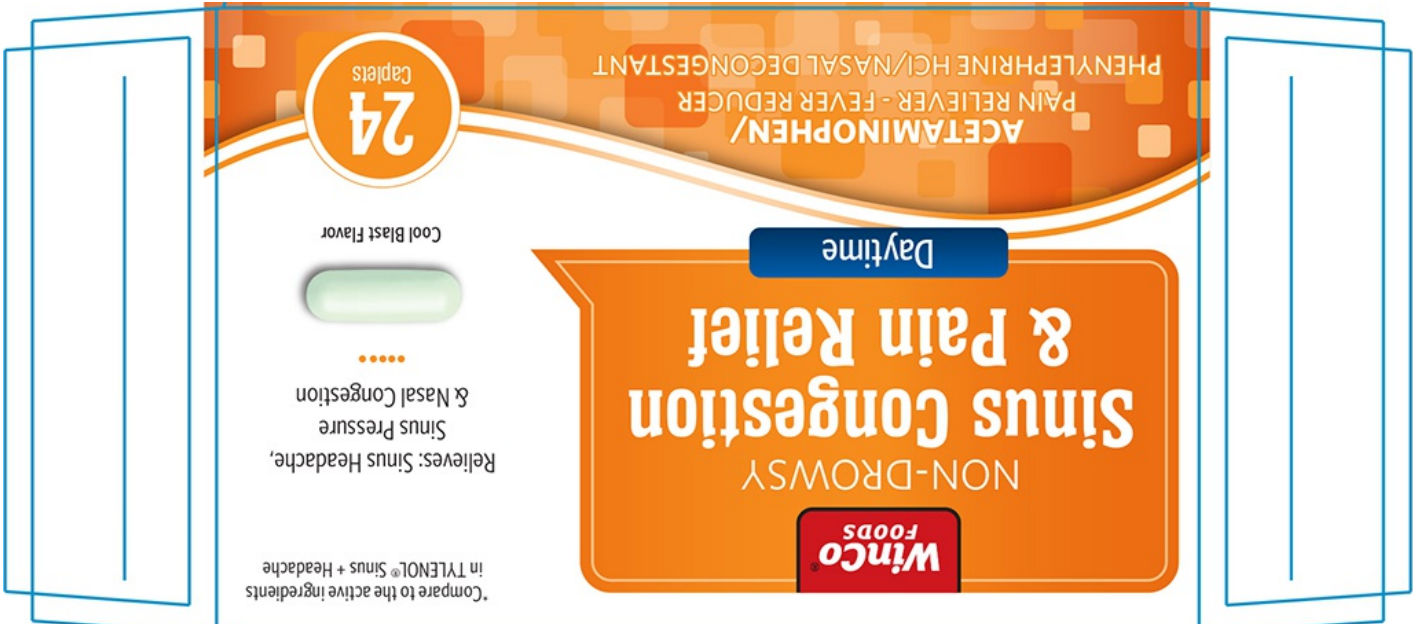
DISTRIBUTED BY:
WINCO FOODS, LLC, BOISE, ID 83704

*This product is not manufactured or distributed by MCNEIL CONSUMER HEALTHCARE, distributor of **TYLENOL® Sinus + Headache**.

50844 REV0316A46608 WF1612

100% SATISFACTION GUARANTEE
Comments & Questions? 800-824-1706

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



Drug Facts
Active ingredients (in each caplet)
 Acetaminophen 325 mg
 Phenylephrine HCl 5 mg

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION
Purpose
 Pain reliever/fever reducer
 Nasal decongestant

Drug Facts (continued)
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B-2150-466C-08-SC
 REV0316A46608

Drug Facts (continued)
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 if you have ever had an allergic reaction to this product or any of its ingredients
Ask a doctor before use if you have
 high blood pressure
 thyroid disease liver disease diabetes heart disease
 difficulty in urination due to enlargement of the prostate gland

Drug Facts (continued)
 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
 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. In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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No Print/ No Varnish
 Lot & Expiry Area

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Drug Facts (continued)
Questions? Call 800-824-1706 Monday - Friday 9am - 4pm MST

Winco 44-466C

SINUS CONGESTION AND PAIN RELIEF NON-DROWSY
 acetaminophen, phenylephrine hcl tablet, film coated
Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67091-213
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
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OPIR32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPVIDONE (UNII: 2S7830E561)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67091-213-24	2 in 1 CARTON	07/26/2005	
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	

Labeler - WinCo Foods, LLC (056098817)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(67091-213)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(67091-213)

Revised: 3/2020

WinCo Foods, LLC