

**SINUS AND HEADACHE- acetaminophen, phenylephrine hcl tablet, film coated
Walgreen Company**

Walgreens 44-466C-SH

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°-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, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

Questions or comments?

1-800-426-9391

Principal display panel**Walgreens**

Compare to the active ingredients
in Tylenol® SINUS + HEADACHE^{††}

WALGREENS
PHARMACIST RECOMMENDED[†]

NDC 0363-4066-08

DAYTIME • NON-DROWSY

Sinus & Headache

ACETAMINOPHEN / PAIN RELIEVER / FEVER REDUCER
PHENYLEPRHINE HCl / NASAL DECONGESTANT

- Relieves hay fever symptoms, minor aches & pains, headache, nasal congestion, sinus congestion & pressure
- Pseudoephedrine free

24 CAPLETS

ACTUAL SIZE

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

[†]Our pharmacists recommend the Walgreens brand.
We invite you to compare to national brands.

^{††}This product is not manufactured or distributed by
Johnson & Johnson Corporation, owner of the
registered trademark Tylenol® SINUS + HEADACHE.

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Walgreens
Compare to the active ingredients
in Tylenol® SINUS + HEADACHE™

DAYTIME • NON-DROWSY
Sinus & Headache
ACETAMINOPHEN / PAIN RELIEVER / FEVER REDUCER
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Drug Facts (continued)

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

Purpose
Pain reliever/fever reducer
Nasal decongestant

Drug Facts (continued)

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:
■ hives ■ rash ■ skin redness
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
■ difficulty in urination due to enlargement of the prostate gland ■ thyroid disease ■ heart disease ■ liver disease ■ high blood pressure

Drug Facts (continued)

Directions ■ **do not take more than directed**
■ adults and children 12 years and over
■ take 2 caplets every 4 hours
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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

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
■ 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.

Drug Facts (continued)

Side effects
■ drowsiness
■ dizziness
■ dry mouth
■ headache
■ heartburn
■ indigestion
■ nausea
■ nervousness
■ rash
■ skin redness
■ sore throat
■ stuffy nose
■ taste changes
■ tiredness
■ throat irritation
■ upset stomach
■ weakness
■ weight gain or loss
■ yellowing of the skin or eyes

Drug Facts (continued)

Other information
■ **TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING**
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Do not print
Lot & Exp

Drug Facts (continued)

Inactive ingredients
corn starch, croscollon, D&G 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, surfactone, tlc, titanium dioxide

Drug Facts (continued)

(Questions or comments? 1-800-424-8391)

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Walgreens 44-466

SINUS AND HEADACHE

acetaminophen, phenylephrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-4066
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)				
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:0363-4066-08	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 Drug	M012	07/26/2005		

Labeler - Walgreen Company (008965063)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(0363-4066) , pack(0363-4066)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(0363-4066)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(0363-4066)

Revised: 1/2024

Walgreen Company