

SINUS AND HEADACHE DAYTIME- acetaminophen, phenylephrine hcl tablet, film coated

L.N.K. International, Inc.

Quality Plus 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:
 - headache
 - minor aches and pains
 - 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

**Quality
+Plus**

NDC 50844-467-08

*Compare to active ingredients in
Tylenol® SINUS + HEADACHE

DAYTIME

**Sinus &
Headache**

Acetaminophen
Phenylephrine HCl

PAIN RELIEVER / FEVER REDUCER
NASAL DECONGESTANT

- Sinus Headache
- Sinus Pressure
- Nasal Congestion
- Pseudoephedrine Free

24 Caplets

NON-DROWSY

ACTUAL SIZE

**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 Kenvue Inc., owner of

the registered trademark Tylenol® SINUS + HEADACHE.

50844 REV0721C46608

Distributed by
LNK INTERNATIONAL, INC.
 60 Arkay Drive,
 Hauppauge, NY 11788
 USA

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

Questions or comments? 1-800-426-9391

DAYTIME Sinus & Headache

Acetaminophen Phenylephrine HCl

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 NASAL DECONGESTANT**

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- Sinus Pressure
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- Pseudoephedrine Free

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Drug Facts (continued)
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Drug Facts (continued)
Stop use and ask a doctor if
 ■ fever, rash, dizziness, or sleeplessness occur
 ■ pain or nasal congestion gets worse or lasts more than 7 days
 ■ new symptoms occur ■ redness or swelling is present
 ■ fever gets worse or lasts more than 3 days
 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)
Directions
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Ask a doctor before use if you have
 ■ difficulty in urination due to enlargement of the prostate gland
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 ■ liver disease ■ high blood pressure

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.

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

**KEEP OUTER PACKAGE FOR
 COMPLETE PRODUCT INFORMATION**

0 50844 46608 1

No Print / No Varnish
 Lot no. & Exp. date

8-1603-466C-08-RR
 REV0721C46608

Quality Plus 44-466C

SINUS AND HEADACHE DAYTIME

acetaminophen, phenylephrine hcl tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50844-467
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)	
CROSPROVIDONE, 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 ALUMINUM LAKE (UNII: 6T47AS764T)	
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:50844-467-02	1 in 1 CARTON	07/26/2005	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50844-467-08	2 in 1 CARTON	07/26/2005	
2		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 - L.N.K. International, Inc. (038154464)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(50844-467) , pack(50844-467)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(50844-467)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(50844-467)

Revised: 4/2024

L.N.K. International, Inc.