

# **SINUS AND HEADACHE- acetaminophen and phenylephrine hcl tablet, film coated**

**Cardinal Health 110, LLC. DBA Leader**

-----  
**Leader 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 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**

**LEADER™**

NDC 70000-0568-1

**Daytime I Non-Drowsy**

**Sinus +  
Headache**

**Acetaminophen**, 325 mg | Phenylephrine HCl, 5 mg  
Pain Reliever / Fever Reducer  
Nasal Decongestant

**Pseudoephedrine-Free**

Sinus Headache & Pressure  
Nasal Congestion

**COMPARE TO  
TYLENOL®**

**SINUS +  
HEADACHE**

active ingredients\*

**24 CAPLETS**

Actual Size

100% Money

Back Guarantee

**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 ORG081846608

DISTRIBUTED BY CARDINAL HEALTH  
 DUBLIN, OHIO 43017  
 www.myleader.com  
 1-800-200-6313

✓ **100%**  
**Money Back**  
**Guarantee**

Return to place of purchase.


© 2020 Cardinal Health. All Rights Reserved. CARDINAL HEALTH, the Cardinal Health LOGO, LEADER, and the Leader LOGO are trademarks or registered trademarks of Cardinal Health. All other marks are the property of their respective owners.

<p><b>Drug Facts (continued)</b></p> <p><b>Uses</b> ■ temporarily relieves these symptoms associated with hay fever or other respiratory allergies, and the common cold:</p> <ul style="list-style-type: none"> <li>■ minor aches and pains</li> <li>■ headache</li> <li>■ nasal congestion</li> <li>■ sinus congestion and pressure</li> </ul>	<p><b>Drug Facts</b></p> <p><b>Active ingredients (in each caplet)</b></p> <p>Acetaminophen 325 mg ..... Pain reliever/fever reducer</p> <p>Phenylephrine HCl 5 mg ..... Nasal decongestant</p>
<p><b>Drug Facts (continued)</b></p> <p>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.</p> <p>When using this product do not exceed recommended dosage.</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> <li>■ nervousness, dizziness, or sleeplessness occur</li> <li>■ pain or nasal congestion gets worse or lasts more than 7 days</li> <li>■ new symptoms occur</li> <li>■ fever gets worse or lasts more than 3 days</li> <li>■ redness or swelling is present</li> </ul> <p>These could be signs of a serious condition.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>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.</p>	<p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>■ helps decongest sinus openings and passages</li> <li>■ promotes sinus drainage</li> <li>■ helps clear nasal passages</li> <li>■ temporarily reduces fever</li> </ul>
<p><b>Directions</b> ■ do not take more than directed</p> <ul style="list-style-type: none"> <li>■ adults and children 12 years and over</li> <li>■ take 2 caplets every 4 hours</li> <li>■ swallow whole – do not crush, chew, or dissolve</li> <li>■ do not take more than 10 caplets in 24 hours</li> <li>■ children under 12 years: ask a doctor</li> </ul>	<p><b>Warnings</b></p> <p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 4,000 mg of acetaminophen in 24 hours</p> <ul style="list-style-type: none"> <li>■ with other drugs containing acetaminophen</li> <li>■ 3 or more alcoholic drinks every day while using this product</li> </ul> <p>Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:</p> <ul style="list-style-type: none"> <li>■ hives</li> <li>■ rash</li> <li>■ skin reddening</li> </ul> <p>If a skin reaction occurs, stop use and seek medical help right away.</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</li> <li>■ 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.</li> <li>■ if you have ever had an allergic reaction to this product or any of its ingredients</li> </ul> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>■ liver disease</li> <li>■ difficulty in urination due to enlargement of the prostate gland</li> <li>■ heart disease</li> <li>■ diabetes</li> <li>■ thyroid disease</li> <li>■ high blood pressure</li> </ul>
<p><b>Other information</b></p> <ul style="list-style-type: none"> <li>■ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN</li> <li>■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)</li> <li>■ see end flap for expiration date and lot number</li> </ul>	

B-0225-466C-08-SC  
 ORG081846608

no print / no varnish area  
lot no. & exp. date

© 2020 Cardinal Health. All Rights Reserved. CARDINAL HEALTH, the Cardinal Health Logo, LEADER, and the leader logo are trademarks or registered trademarks of Cardinal Health. All other marks are the property of their respective owners.



NDC 70000-0568-1

**Daytime | Non-Drowsy**


# Sinus + Headache

**Acetaminophen, 325 mg | Phenylephrine HCl, 5 mg**  
Pain Reliever / Fever Reducer  
Nasal Decongestant

**Pseudoephedrine-Free**

Sinus Headache & Pressure  
Nasal Congestion

**COMPARE TO  
TYLENOL®  
SINUS +  
HEADACHE**  
active ingredients\*



Actual Size

**100% Money  
Back Guarantee**

CIN 5653191 REV. 8/20



0 96295 13990 7

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 ORG081846608

DISTRIBUTED BY: CARDINAL HEALTH  
DUBLIN, OHIO 43017  
www.myleader.com  
1-800-200-6313

Return to place of purchase.

**Drug Facts** (continued)

**Inactive ingredients** com starch, crospovidone, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C red #40 aluminum lake, FD&C flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, sucralose, talc, titanium dioxide

**Drug Facts** (continued)  
sulficon dioxide, sodium starch glycolate, stearic acid, Questions or comments? 1-800-426-9391

**Leader 44-466C**

<b>SINUS AND HEADACHE</b>			
acetaminophen and phenylephrine hcl tablet, film coated			
Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0568
<b>Route of Administration</b>	ORAL		
Active Ingredient/Active Moiety			
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg	
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (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 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:70000-0568-1	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** - Cardinal Health 110, LLC. DBA Leader (063997360)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(70000-0568) , pack(70000-0568)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(70000-0568)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(70000-0568)

Revised: 8/2024

Cardinal Health 110, LLC. DBA Leader