

**SINUS PRESSURE AND PAIN MAXIMUM STRENGTH- acetaminophen,
phenylephrine hcl tablet**
Cardinal Health 110, LLC. DBA Leader

Leader 44-502

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 upper respiratory allergies, and the common cold:
 - minor aches and pains
 - nasal congestion
 - headache
 - sinus congestion and pressure
- promotes sinus drainage
- 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:

- skin reddening
- blisters
- rash

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

- heart disease
- thyroid disease
- diabetes
- liver disease
- high blood pressure
- 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 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 use more than directed**
- adults and children 12 years and over
 - take 2 caplets every 4 hours
 - 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, croscarmellose sodium, crospovidone, FD&C yellow #6 aluminum lake, magnesium stearate, microcrystalline cellulose, povidone, silicon dioxide, stearic acid

Questions or comments?

1-800-426-9391

Principal display panel

LEADER™

NDC 70000-0161-1

Maximum Strength

Sinus Pressure + Pain

Acetaminophen | Pain Reliever / Fever Reducer
Phenylephrine HCl | Nasal Decongestant

Non-Drowsy

Relieves:

Sinus Headache, Sinus Pressure,
Nasal Congestion

24 CAPLETS

Actual Size

**COMPARE TO
SUDAFED PE® SINUS
PRESSURE + PAIN**

active ingredients*

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**

CIN 5294335 REV. 3/21

*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Sudafed PE® Sinus Pressure + Pain 50844 REV0820B50208

CardinalHealth™

DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017

www.myleader.com 1-800-200-6313

Essential to Care™ since 1979

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of their respective owners.

100% Money Back Guarantee

Return to place of purchase if not satisfied.

LEADER²

NDC 70000-0161-1

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Sinus Pressure + Pain

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Relieves:
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24 CAPLETS



Actual Size

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PRESSURE + PAIN
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Drug Facts

KEEP OUTER PACKAGE FOR COMPLETE
PRODUCT INFORMATION

Purpose

Phenylephrine HCl 5 mg
Acetaminophen 325 mg
Pain reliever/fever reducer
Nasal decongestant

Uses

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

promotes sinus drainage ■ temporarily reduces fever

Maximum Strength
Sinus Pressure + Pain
Acetaminophen | Pain Reliever / Fever Reducer
Phenylephrine HCl | Nasal Decongestant

LEADER²

CIN 5294335

REV. 3/21



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PACKAGE IS OPENED OR IF BLISTER
UNIT IS TORN, BROKEN OR SHOWS
ANY SIGNS OF TAMPERING

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

Drug Facts (continued)

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Questions or comments? 1-800-426-9391

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B-0225-502-08
REV0820850208

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: ■ skin redness ■ blisters ■ rash
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
■ heart disease ■ thyroid disease ■ diabetes
■ liver disease ■ high blood pressure
■ 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.

Drug Facts (continued)

Directions
■ do not use more than directed
■ adults and children 12 years and over
■ take 2 caplets every 4 hours
■ do not take more than 10 caplets in 24 hours
■ children under 12 years: ask a doctor
Other information
■ 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, croscarmellose sodium, croscopolone, FD&C yellow #6 aluminum lake, magnesium stearate, microcrystalline cellulose, polydioxane, silicon dioxide, stearic acid

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.
If pregnant or breast-feeding, ask a health professional before use. These could be signs of a serious condition.
■ redness or swelling is present ■ new symptoms occur
■ fever gets worse or lasts more than 3 days
■ pain or nasal congestion gets worse or lasts more than 7 days
■ nervousness, dizziness, or sleeplessness occur
Stop use and ask a doctor if:
When using this product do not exceed recommended dosage.

Leader 44-502

SINUS PRESSURE AND PAIN MAXIMUM STRENGTH

acetaminophen, phenylephrine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0161
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)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C YELLOW NO. 6 ALUMINUM LAKE (UNII: GYP6Z2JR6Q)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	orange	Score	no score
Shape	OVAL	Size	18mm
Flavor		Imprint Code	44;502
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0161-1	2 in 1 CARTON	06/23/2005	
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	06/23/2005	

Labeler - Cardinal Health 110, LLC. DBA Leader (063997360)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(70000-0161) , pack(70000-0161)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(70000-0161)

Revised: 4/2025

Cardinal Health 110, LLC. DBA Leader