SINUS PRESSURE PAIN MAXIMUM STRENGTH, NON-DROWSY- acetaminophen, phenylephrine hcl tablet Amerisource Bergen

Good Neighbor Pharmacy 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

GOOD NEIGHBOR PHARMACY®

Compare to SUDAFED PE® SINUS PRESSURE + PAIN active ingredients*

NDC 46122-443-62

MAXIMUM STRENGTH

Sinus Pressure/Pain acetaminophen, phenylephrine HCl pain reliever/fever reducer & nasal decongestant

Non-Drowsy

Relief of:

• Sinus Headache • Sinus Pressure • Nasal Congestion

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

Distributed By Amerisource Bergen 1300 Morris Drive Chesterbrook, PA 19087 Questions or Concerns? www.mygnp.com

GOOD NEIGHBOR PHARMACY BRAND PRODUCTS

SATISFACTION GUARANTEED

*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark SUDAFED PE® SINUS PRESSURE + PAIN.

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SINUS PRESSURE PAIN MAXIMUM STRENGTH, NON-DROWSY

acetaminophen, phenylephrine hcl tablet

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:46122-443

Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D)	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)			
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)			
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				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:46122- 443-62	2 in 1 CARTON	06/23/2005			
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product				

Marketing In	formation		
Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC Monograph Drug	M012	06/23/2005	

Labeler - Amerisource Bergen (007914906)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(46122-443) , pack(46122-443)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(46122-443)

Revised: 11/2023 Amerisource Bergen