SINU-PHEN PLUS SINUS PAIN AND PRESSURE - acetaminophen, phenylephrine hydrochloride tablet Wildman Business Group

ACTIVE INGREDIENT

Active ingredients (in each tablet)

Acetaminophen 500mg

Phenylephrine HCI 5mg

PURPOSE

Purpose

Pain reliever/fever reducer

Nasal decongestant

INDICATIONS & USAGE

Uses

temporarily relieves these common cold/flu symptoms:

- nasal congestion
- headache
- minor aches and pains
- stuffy nose
- sinus congestion and pressure temporarily reduces fever

WARNINGS

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
- o 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

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.
- for more than 10 days unless directed by a doctor

ASK DOCTOR

Ask a doctor before use if you have

- liver disease
- thyroid disease
- diabetes
- high blood pressure
- heart disease
- trouble urinating due to an enlarged prostate gland

ASK DOCTOR/PHARMACIST

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin

WHEN USING

When using this product do not exceed recommended dosage.

STOP USE

Stop use and ask a doctor if

- you get nervous, dizzy, or sleepless
- 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 appear

These could be signs of a serious condition.

PREGNANCY OR BREAST FEEDING

If pregnant or breast-feeding, ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children.

Overdose warning:

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if

you do not notice any signs or symptoms.

DOSAGE & ADMINISTRATION

Directions

do not use more than directed

Adults and children: (12 years and over) Take 2 tablets every 6 hours. Do not take more than 8 tablets in 24 hours.

Children under 12 years: Ask a doctor

OTHER SAFETY INFORMATION

Other information

- store at room temperature 59°-86°F (15°-30°C)
- tamper evident sealed packets
- do not use any opened or torn packets
- avoid excessive heat and humidity

INACTIVE INGREDIENT

Inactive ingredients

corn starch, crospovidone, hypromelloses, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, stearic acid.

QUESTIONS

Questions or comments? (888) 602-0288

PRINCIPAL DISPLAY PANEL - 250 Tablet Box Label

Sinu-Phen Plus

Sinus Pain & Pressure

Acetaminophen 500 mg

Phenylephrine HCl 5 mg

Pull to Open

Fast Relief of:

- Fever
- Nasal Congestion
- Body Aches
- Sinus Pain

The Provision

First Aid

Line™

BY WILDMAN

250 tablets

2 Per Packet

2546 2546







2 Per Packet

Fast Relief of:

- Fever
- Nasal Congestion
- Body Aches
- Sinus Pain



Acetaminophen 500 mg Phenylephrine HCI 5 mg



Fast Relief of:

- Fever
- Nasal Congestion
- · Body Aches
- Sinus Pain



250 Tablets 2 Per Packet

Manufactured for Provision by Wildman Warsaw, IN 46580







5248

2546

Drug Facts

Active ingredient (in each tablet) Purpose Phenylephrine HCI 5 mg... . Nasal decongestant

Uses

emporarily relieves these common cold/flu symptoms:

■ nasal congestion ■ headache ■ minor aches and pain ■ sinus congestion and pressure mporarily reduces fever

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- 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

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 week 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.

for more than 10 days unless directed by a doctor

Ask a doctor before use if you have

- liver disease thyroid disease high blood pressure heart disease
- trouble urinating due to an enlarged 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 losage.

Drug Facts (continued)

Stop use and ask a doctor if

- you get nervous, dizzy, or sleepless
- 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 appe
- 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.

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Adults and Take 2 tablets every 6 hours. Do not take children: (12 more than 8 tablets in 24 hours. years and over) Children under Ask a doctor 12 years:

Other information

- store at room temperature 59°-86°F (15°-30°C)
- tamper evident sealed packets

Inactive ingredients

- do not use any opened or torn packets
- avoid excessive heat and humidity

com starch, crospovidone, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch

Questions or comments?

(888) 602-0288 Manufactured for: Provision by Wildman Warsaw, IN 46580

Retain carton for complete product information



Acetaminophen 500 mg Phenylephrine HCl 5 mg

Pull to Open



Fast Relief of:

- Fever
- Nasal Congestion
- Body Aches
- Sinus Pain



250 Tablets

2 Per Packet

SINU-PHEN PLUS SINUS PAIN AND PRESSURE

acetaminophen, phenylephrine hydrochloride tablet

Product Information

HUMAN OTC DRUG Product Type Item Code (Source) NDC:84269-2546

ORAL **Route of Administration**

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (Phenylephrine - UNII: 1W5297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	Strength
CROSPOVIDONE (120 .MU.M) (UNII: 68401960MK)	
POVIDONE (UNII: FZ989GH94E)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	white (white)	Score	no score
Shape	ROUND (ROUND)	Size	12mm
Flavor		Imprint Code	AZ;261
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84269- 2546-2	125 in 1 BOX	07/01/2024	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:84269- 2546-1	50 in 1 BOX	07/01/2024	
2		2 in 1 PACKET; 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	07/01/2024	

Labeler - Wildman Business Group (016677338)

Establishment			
Name	Address	ID/FEI	Business Operations
Allegiant Health		079501930	MANUFACTURE(84269-2546)

Establishment			
Name	Address	ID/FEI	Business Operations
Medique Products		086911794	PACK(84269-2546)

Establishment

Name	Address	ID/FEI	Business Operations
Prestige Packaging		080667761	PACK(84269-2546)

Revised: 7/2024 Wildman Business Group