

SINUS PLUS HEADACHE DAY AND NIGHT- acetaminophen, chlorpheniramine maleate, and phenylephrine hydrochloride
TOPCO ASSOCIATES LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

1149B-TCR-2021-1112

SINUS + HEADACHE DAY

Drug Facts

<i>Active ingredients (in each day caplet)</i>	<i>Purpose</i>
Acetaminophen 325 mg	Pain reliever/fever reducer
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

■ temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold:

- headache
- sinus congestion and pressure
- nasal congestion
- minor aches and pains
- helps decongest sinus openings and passages
- promotes sinus drainage
- helps clear nasal passages
- temporarily reduces fever

SINUS + HEADACHE NIGHT

Drug Facts

<i>Active ingredients (in each night caplet)</i>	<i>Purpose</i>
Acetaminophen 325 mg	Pain reliever/fever reducer
Chlorpheniramine maleate 2 mg	Antihistamine
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

■ temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold:

- headache
- sinus congestion and pressure
- nasal congestion
- runny nose and sneezing
- minor aches and pains
- helps decongest sinus openings and passages
- promotes sinus drainage
- helps clear nasal passages
- temporarily reduces fever

Warnings

Liver warning

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. 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

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

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

■ do not exceed recommended dosage

In addition, when using Sinus + Headache Night:

- excitability may occur, especially in children
- drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

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.

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.

Directions

■ do not take more than directed (see overdose warning)

- do not take Day and Night caplets at the same time
- do not take more than a total of 10 caplets in 24 hours

adults and children 12 years and over	<ul style="list-style-type: none"> ■ take 2 caplets every 4 hours ■ swallow whole; do not crush, chew, or dissolve
children	

under 12 years	■ ask a doctor
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Other information

- store between 20-25°C (68-77°F) in a dry place
- retain carton for complete product information and warnings

Inactive ingredients

SINUS + HEADACHE DAY

acesulfame potassium, colloidal silicon dioxide, croscarmellose sodium, 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, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

SINUS + HEADACHE NIGHT

acesulfame potassium, colloidal silicon dioxide, corn starch, croscarmellose sodium, crospovidone, flavor, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

PRINCIPAL DISPLAY PANEL

TopCare® health

NDC 36800-349-02

For Adults

Sinus + Headache Day + Night

DAYTIME

NON-DROWSY

PAIN RELIEVER/FEVER REDUCER - ACETAMINOPHEN

NASAL DECONGESTANT - PHENYLEPHRINE HCl

DAY CAPLET RELIEVES:

- Sinus Headache
- Sinus Pressure
- Nasal Congestion

actual size

12 COOL TASTE CAPLETS

8 COOL TASTE CAPLETS

<p>Sinus + Headache Night</p>		<p>Sinus + Headache Day</p>	
<p>DO NOT TAKE MORE THAN A TOTAL OF 10 CAPLETS IN A 24-HOUR PERIOD.</p> <p>TAKE ONLY AS DIRECTED.</p>			
<p>Drug Facts</p> <p>Active Ingredients (in each Night caplet) Acetaminophen 325 mg., Pain reliever/Fever reducer Chlorpheniramine maleate 2 mg., Antihistamine Phenylephrine HCl 5 mg., Nasal decongestant</p> <p>Purpose</p>		<p>Drug Facts</p> <p>Active Ingredients (in each Day caplet) Acetaminophen 325 mg., Pain reliever/Fever reducer Phenylephrine HCl 5 mg., Nasal decongestant</p> <p>Purpose</p>	
<p>Uses ■ temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold: ■ headache ■ minor aches and pains ■ nasal congestion ■ runny nose and sneezing ■ sinus congestion and pressure ■ helps decongest sinus openings and passages ■ promotes sinus drainage ■ helps clear nasal passages ■ temporarily reduce fever</p>		<p>Uses ■ temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold: ■ headache ■ nasal congestion ■ minor aches and pains ■ sinus congestion and pressure ■ helps decongest sinus openings and passages ■ promotes sinus drainage ■ helps clear nasal passages ■ temporarily reduce fever</p>	
<p>Warnings This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. 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</p> <p>Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash</p> <p>If a skin reaction occurs, stop use and seek medical help right away.</p>		<p>Do not use</p> <ul style="list-style-type: none"> ■ 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 	
<p align="center">LIFT PANEL FOR MORE DRUG FACTS INFORMATION</p>			

Sinus + Headache Day + Night

For Adults



SINUS PLUS HEADACHE DAY AND NIGHT

acetaminophen, chlorpheniramine maleate, and phenylephrine hydrochloride kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-349
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-349-02	1 in 1 CARTON	06/18/2021	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BLISTER PACK	12
Part 2	1 BLISTER PACK	8

Part 1 of 2

ACETAMINOPHEN, PHENYLEPHRINE HYDROCHLORIDE

acetaminophen, and phenylephrine hydrochloride tablet, coated

Product Information

Route of Administration	ORAL
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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
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Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL (capsule-shaped)	Size	17mm
Flavor	MINT	Imprint Code	AAA;1123
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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 final	part341		

Part 2 of 2

ACETAMINOPHEN, CHLORPHENIRAMINE MALEATE, PHENYLEPHRINE HYDROCHLORIDE

acetaminophen, chlorpheniramine maleate, and phenylephrine hydrochloride tablet, coated

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPVIDONE (UNII: 2S7830E561)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	

Product Characteristics

Color	white (Off-White)	Score	no score
Shape	OVAL (capsule-shaped)	Size	17mm
Flavor	MINT	Imprint Code	AAA;1128
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 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 final	part341		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/18/2021	

Labeler - TOPCO ASSOCIATES LLC (006935977)

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