

ACETAMINOPHEN, PHENYLEPHRINE HYDROCHLORIDE- acetaminophen and phenylephrine hydrochloride tablet, coated
AAA Pharmaceutical, Inc.

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.

RES - 1123 - 2019-1012

Drug Facts

<i>Active ingredients (in each 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

Warnings

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

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

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.

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)**

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 • do not take more than 10 caplets in 24 hours
children under 12 years	<ul style="list-style-type: none"> • ask a doctor

Other information

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

Inactive ingredients

acesulfame potassium, colloidal silicon dioxide, croscarmellose sodium, D&C yellow #10, FD&C blue #1, flavor, hypromellose, lactose, magnesium stearate, povidone, pregelatinized starch, propylene glycol, sodium starch glycolate, stearic acid, titanium dioxide

Distributed by:

AAA Pharmaceutical, Inc.
681 Main Street
Lumberton, NJ 08048

PRINCIPAL DISPLAY PANEL - 24 Tablet Blister Pack Carton

RESTORE u

NDC 57344-123-05

†COMPARE TO THE ACTIVE
INGREDIENTS IN TYLENOL® SINUS
CONGESTION & PAIN - DAYTIME

**See New Warnings
Information & Directions**

DAY TIME

NON-DROWSY

Sinus

For

Adults

CONGESTION & PAIN

Pain Reliever/Fever Reducer, Nasal Decongestant

- Sinus Headache – **Acetaminophen**
- Nasal Congestion/Sinus Pressure – Phenylephrine HCl

24 CAPLETS

NC

<p>Drug Facts (continued)</p> <p>Warnings 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 or 3 or more alcoholic drinks every day while using this product.</p> <p>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.</p> <p>Ask a doctor before use if you have liver disease ■ heart disease ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland</p>	<p>Drug Facts (continued)</p> <p>Directions do not take more than directed (see overdose warning) 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 ■ ask a doctor children under 12 years</p>
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NC

NC

<p>Drug Facts (continued)</p> <p>Active Ingredients (in each caplet) Acetaminophen 325 mg.....Pain reliever/fever reducer Phenylephrine HCl 5 mg.....Nasal decongestant</p> <p>Uses temporarily relieves these symptoms associated with hay fever ■ temporarily reduces fever ■ promotes sinus drainage ■ helps clear nasal passages ■ helps decongest sinus openings and passages ■ minor aches and pains ■ nasal congestion ■ sinus congestion and pressure ■ headache ■ or other upper respiratory allergies, and the common cold.</p> <p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if fever gets worse or lasts more than 3 days ■ pain or nasal congestion gets worse or lasts more than 7 days ■ redness or swelling is present ■ new symptoms occur ■ these could be signs of a serious condition.</p> <p>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.</p>	<p>Drug Facts (continued)</p> <p>When using this product do not exceed recommended dosage</p> <p>Stop use and ask a doctor if blood thinning drug warfarin ■ nervousness, dizziness, or sleepiness 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.</p> <p>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.</p>
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See New Warnings Information & Directions

Sinus For Adults

CONGESTION & PAIN

Pain Reliever/Fever Reducer, Nasal Decongestant

- Sinus Headache – **Acetaminophen**
- Nasal Congestion/Sinus Pressure – **Phenylephrine HCl**

24 CAPLETS

DAYTIME NON-DROWSY



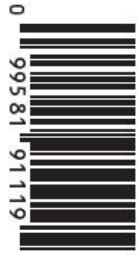
Distributed by:
AAA Pharmaceutical, Inc.
681 Main Street
Lumberton, NJ 08048

†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® Sinus Congestion and Pain.

DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN

F112305RES_R0

<p>Drug Facts (continued)</p> <p>Other information store between 20-25°C (68-77°F) in a dry place ■ retain caution for complete product information</p> <p>Drug Facts (continued)</p> <p>Other information FD&C blue #1, flavoc, hypromellose, lactose, magnesium stearate, povidone, pregelatinized starch, propylene glycol, sodium starch glycolate, stearic acid, titanium dioxide</p>	<p>Drug Facts (continued)</p> <p>Inactive ingredients silicon dioxide, croscarmellose sodium, D & C yellow #10</p>
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acetaminophen and phenylephrine hydrochloride tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57344-123
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
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: HBR47K3TBD)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	17mm
Flavor	MINT	Imprint Code	AAA;1114
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57344-123-05	2 in 1 CARTON	04/30/2012	
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
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Labeler - AAA Pharmaceutical, Inc. (181192162)

Revised: 10/2019

AAA Pharmaceutical, Inc.