

ACETAMINOPHEN CONGESTION AND PAIN- acetaminophen, phenylephrine hcl tablet, film coated

Major Pharmaceuticals

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.

Major Pharmaceuticals Acetaminophen Congestion and Pain Drug Facts

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:
- 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. 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

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

Inactive ingredients

acesulfame potassium, carnauba wax, crospovidone, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C red #40 aluminum lake, flavor, lecithin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

Questions or comments?

1-800-616-2471

Principal Display Panel

Compare to the active ingredients in Tylenol® SINUS + HEADACHE

Acetaminophen

CONGESTION AND PAIN

CAPLETS

Acetaminophen – Pain reliever / Fever reducer

Phenylephrine HCl – Nasal decongestant

Relieves: Sinus Headache, Sinus Pressure & Nasal Congestion

Actual Size

For Adults

24 CAPLETS

with cool Blast Flavor

NON-DROWSY

DAYTIME

27262 5C C3

Drug Facts (continued)

Directions ■ do not take more than directed (see overdose warning) ■ 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 if children under 12 years

Drug Facts (continued)

Inactive Ingredients acesulfame potassium, carnuba wax, croscopolone, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C red #40 aluminum lake, flavor, lecithin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

Drug Facts (continued)

Warnings ■ 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.

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 ■ prevents sinus damage ■ helps clear nasal passages ■ temporarily reduces fever

Active Ingredients (in each caplet)

Acetaminophen 325 mg
 Pain reliever/fever reducer

Phenylephrine HCl 5 mg
 Nasal decongestant

Purpose

Drug Facts (continued)

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.

Drug Facts (continued)

Questions or comments? 1-800-616-2471

Shore at 20-25°C (68-77°F).

Distributed by
MAJOR PHARMACEUTICALS
 17177 N Laurel Park Drive, Suite 233
 Livonia, MI 48152
 M-05 REV. 04/18
 Pa-Order No. 700980

NDC 0904-6760-24
 Compare to the active ingredients
 in Tylenol® SINUS + HEADACHE*

MAJOR®

Acetaminophen

CONGESTION AND PAIN

CAPLETS

Acetaminophen - Pain reliever / Fever reducer
 Phenylephrine HCl - Nasal decongestant

Relieves: Sinus Headache,
 Sinus Pressure & Nasal Congestion

For Adults

24 CAPLETS with Cool Blast Flavor

NON-DROWSY DAYTIME



Actual Size



DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN

*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® SINUS + HEADACHE



ACETAMINOPHEN CONGESTION AND PAIN

acetaminophen, phenylephrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6760
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)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSPVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POVIDONES (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color	GREEN	Score	no score
Shape	OVAL	Size	16mm
Flavor	VANILLA (menthol)	Imprint Code	L272
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6760-24	12 in 1 CARTON	01/15/2007	
1		2 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 - Major Pharmaceuticals (191427277)

Revised: 8/2018

Major Pharmaceuticals