

COLD AND HEAD CONGESTION SEVERE- acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated
CHAIN DRUG CONSORTIUM

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.

1175-PRV-2020-0902

Drug Facts

<i>Active ingredients (in each caplet)</i>	<i>Purpose</i>
Acetaminophen 325 mg	Pain reliever/fever reducer
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- for the temporary relief of the following cold symptoms:
 - minor aches and pains
 - headache
 - sore throat
 - nasal congestion
 - sinus congestion and pressure
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- 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

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.

Sore throat warning

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

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
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

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, nasal congestion, or cough 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
- cough comes back or occurs with rash or headache that lasts

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	<ul style="list-style-type: none"> ▪ ask a doctor

years |

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, crospovidone, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

Questions or comments?

1-844-705-4384

PRINCIPAL DISPLAY PANEL

Premier Value®

COMPARE TO THE ACTIVE INGREDIENTS IN TYLENOL® COLD + HEAD CONGESTION SEVERE†

FOR ADULTS

Cold & Head

CONGESTION SEVERE

Acetaminophen, Phenylephrine HCl, Guaifenesin

Pain Reliever/Fever Reducer, Nasal Decongestant, Expectorant

Relieves:

- Headache & Body Aches
- Nasal Congestion
- Fever & Sore Throat
- Mucus & Chest Congestion

ACTUAL SIZE

24 COOL TASTE CAPLETS

Drug Facts (continued)

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

Inactive ingredients
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Questions or comments?
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Drug Facts (continued)

Warnings (continued)
 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 ■ Symptoms may include: ■ skin redness ■ blisters ■ rash ■ Allergy alert: acetaminophen may cause severe skin reactions. If a skin reaction occurs, stop use and seek medical help right away. ■ Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

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 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

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
 children under 12 years
 ■ ask a doctor

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.

Keep out of reach of children.
 If pregnant or breast-feeding, ask a health professional before use. These could be signs of a serious condition.
 ■ cough comes back or occurs with rash or headache that lasts
 ■ redness or swelling is present
 ■ fever gets worse or lasts more than 3 days
 ■ pain, nasal congestion, or cough gets worse or lasts more than 7 days
 ■ nervousness, dizziness, or sleeplessness occur
 ■ Stop use and ask a doctor if

When using this product do not exceed recommended dosage
 ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
 ■ Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

Drug Facts (continued)



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Drug Facts (continued)

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 Phenylephrine HCl 5 mg
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 Guaifenesin 200 mg
 Expectorant

Purpose
 Pain reliever/fever reducer, Nasal decongestant, Expectorant

Uses
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 ■ temporarily reduces fever

DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN



This product is not manufactured or distributed by Medical Consumer Healthcare, distributor of Mylenol® Cold + Head Congestion Severe.

Distributed By:
 Pharmacy Value Alliance, LLC
 407 East Lancaster Avenue
 Wayne, PA 19087

If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

COMPARE TO THE ACTIVE INGREDIENTS IN TYLENOL® COLD + HEAD CONGESTION SEVERE

FOR ADULTS

Premier Value®

Cold & Head CONGESTION SEVERE

Acetaminophen, Phenylephrine HCl, Guaifenesin
 Pain Reliever/Fever Reducer, Nasal Decongestant, Expectorant

Relieves:

- Headache & Body Aches
- Fever & Sore Throat
- Nasal Congestion
- Mucus & Chest Congestion

24 COOL TASTE CAPLETS

ACTUAL SIZE

acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-717
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 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)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (UNII: 2S7830E561)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	19mm
Flavor	MINT	Imprint Code	AAA;1119
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-717-24	2 in 1 CARTON	06/01/2015	
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	06/01/2015	

Labeler - CHAIN DRUG CONSORTIUM (101668460)

Revised: 9/2020

CHAIN DRUG CONSORTIUM