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

1175-PRV-2020-0902

Drug Facts

Active ingredients (in each caplet)	Purpose
Acetaminophen 325 mg	Pain reliever/fever
Acctaninophen 323 mg	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, perists 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	 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

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 CongestionACTUAL SIZE24 COOL TASTE CAPLETS

colloidal allicon dioxide, croscarmellose sodium, crospovidone, Inactive ingredients acesulfame potassium

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

> > Drug Facts (continued)

1-844-705-4384 nestions or comments?

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

Drug Facts (continued)

I.S. Asgua children under ■ 92K 9 QOCIOL years and over ■ QO UOL LEKKE LUCIG AUSU JO CEIDIGLE IU 74 DOUILE children 12 ■ swallow whole – do not crush, chew, or dissolve ■ fake 2 caplets every 4 hours adults and

do not take more than directed (see overdose warning)

nogee sult sidus or symptoms. attention is critical for adults as well as for children even if you do not Poison Control Center right away (1-800-222-1222). Quick medical Overdose warning: In case of overdose, get medical help or contact a 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
- uew symptoms occur redness or swelling is present ■ fever gets worse or lasts more than 3 days
- pain, nasal congestion, or cough gets worse of lasts more than 7 days ■ Dervousness, dizziness, or sleeplessness occur Stop use and ask a doctor if

When using this product do not exceed recommended dosage thinning drug warfarin

Ask a doctor or pharmacist before use if you are taking the blood condu that occurs with too much philegm (mucus)

curonic pronchitis, or emphysema persistent or chronic cough such as occurs with smoking, asthma,

Drug Facts (continued)

 trouble unnating due to an enlarged prostate gland ■ high blood pressure ■ thyroid disease ■ heart disease ■ liver disease ■ diabetes Ask a doctor before use if you have stnaibargni

 if you have ever had an allergic reaction to this product or any of its MAOI, ask a doctor or pharmacist before taking this product. MAOI drug. If you do not know if your prescription drug contains an conditions, or Parkinson's disease), or for 2 weeks after stopping the (MAOI) (certain drugs for depression, psychiatric, or emotional

IL You are now taking a prescription monoamine oxidase inhibitor acetaminophen, ask a doctor or pharmacist.

nonprescription). If you are not sure whether a drug contains with any other drug containing acetaminophen (prescription or

vomiting, consult a doctor promptly.

days, is accompanied or followed by fever, headache, rash, nausea, or Sore throat warning: If sore throat is severe, persists for more than 2 It a skin reaction occurs, stop use and seek medical help right away. Symptoms may include: • skin reddening • blisters • rash Allergy alert: acetaminophen may cause severe skin reactions.

- 3 or more alcoholic drinks every day while using this product
 - with other drugs containing acetaminophen
 - more than 4,000 mg of acetaminophen in 24 hours hours. Severe liver damage may occur if you take

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

Drug Facts (continued)

Nasal decongestant

Expectorant

Purpose

Active ingredients (in each caplet)

Рћепујерћгіпе НСІ 5 тд

Guaifenesin 200 mg.

Drug Facts

 temporarily reduces fever wske condus wore productive

 helps loosen phlegm (mucus) and thin bronchial secretions to ainus congestion and pressure ■ nasal congestion ■ minor aches and pains ■ µegggcue NSGS . Tor the temporary relief of the following cold symptoms:

nund racts (confined)

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

FOR ADULTS



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

ACTUAL SIZE



24 GOOL TASTE CAPLETS

†This product is not manufactured distributed by McNeil Consumer Healthcare, distributor of Tylenol[©] Cold + Head Congestion Severe.

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

DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN

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

COLD AND HEAD CONGESTION SEVERE

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: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
CROSPOVIDONE (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: FZ 989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	

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

	Packaging					
7	# Item Code Package Description		Marketing Start Date	Marketing End Date		
:	NDC:68016- 717-24	2 in 1 CARTON	06/01/2015	07/31/2026		
:	L	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 Drug	M012	06/01/2015	07/31/2026

Labeler - CHAIN DRUG CONSORTIUM (101668460)

Revised: 10/2024 CHAIN DRUG CONSORTIUM