COLD HEAD CONGESTION SEVERE- acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated HEB

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.

HEB - 1175 - 2019-1004

Drug Facts

Active ingredients (in each caplet)	Purpose
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, 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

Compare to Tylenol Cold + Head Congestion Severe Caplets active ingredients

NDC 37808-775-02

HEB

Cold & Head Congestion Severe

Acetaminophen / Pain Reliever/Fever Reducer

Guaifenesin / Expectorant

Phenylephrine HCI / Nasal Decongestant

Cold, Head Congestion

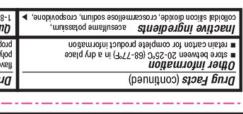
COOL TASTE

For Adults

Relief of:

Head & Body Aches, Fever, Sore Throat Nasal Congestion, Mucus & Chest Congestion actual size

24 CAPLETS



1-844-705-4384 unestions or comments?

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

Drug Facts (continued)

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Drug Facts (continued)



Nasal decongestant

Expectorant Tever reducer

Purpose

(in each caplet) Active ingredients

NDC 37808-775-02

Бле пујерћиће НС1 5 mg Guaifenesin 200 mg.

Drug Facts

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Drug Facts (continued)

Compare to Tylenol® Cold + Head Congestion Severe Caplets active ingredients

Cold & Head Congestion Say

Acetaminophen / Pain Reliever/Fever Reducer Guaifenesin / Expectorant Phenylephrine HCI / Nasal Decongestant

Cold, Head Congestion

For Adults

Relief of:

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

24 CAPLETS

ctual

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

DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN

DISTRIBUTED BY H-E-B® SAN ANTONIO, TX 7820

COLD HEAD CONGESTION SEVERE

acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-775
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
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (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					
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
:	NDC:37808- 775-02	2 in 1 CARTON	04/01/2018			
:	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 final	part341	04/01/2018		

Labeler - HEB (007924756)

Revised: 12/2022 HEB