

COLD PLUS HEAD CONGESTION SEVERE- acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated
DISCOUNT DRUG MART

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.

DDM-1175-2020-0810

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	■ 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	■ 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

PRINCIPAL DISPLAY PANEL

DISCOUNT DRUG MART FOOD FAIR

NDC 53943-175-02

†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

RELIEF OF:

- HEADACHE + BODY ACHES
- FEVER + SORE THROAT
- NASAL CONGESTION
- MUCUS + CHEST CONGESTION

24 COOL TASTE CAPLETS

Actual Size

E117502DDM R1



Other information

- same between 20-25 °C (60-77 °F) in a dry place
- retain carton for complete product information

Inactive ingredients acesulfame potassium, colloidal silicon dioxide, croscarmellose sodium, crospovidone, ►

flavor, magnesium stearate, malt

polyethylene glycol, polyvinyl alcohol, polyvinylidene fluoride, polypropylene glycol, stearic acid, talc, titanium dioxide,

Warnings

ADVERSE REACTIONS: This product contains acetaminophen; the maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24

- 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

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 dexamethasone (prescription or nonprescription). If you are not sure whether a drug contains

■ If you are now taking a prescription monoamine oxidase inhibitor (MAOI), do not take this medicine. MAOIs are used to treat depression, Parkinson's disease, and certain types of high blood pressure.

(MWU) (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 ■ diabetes ■ heart disease ■ high blood pressure ■ thyroid disease

■ trouble urinating due to an enlarged prostate gland

Uses ■ for the temporary relief of

- nasal congestion
- minor aches and pains
- headache
- sinus congestion and pressure
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily reduces fever

†Compare to the active ingredients
in Tylenol® Cold + Head Congestion Severe

NDC 53943-175-02



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

- HEADACHE + BODY ACHES
- NASAL CONGESTION
- FEVER + SORE THROAT
- MUCUS + CHEST CONGESTION



COLD PLUS HEAD CONGESTION SEVERE

acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated				
Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:53943-175
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)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
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: 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:53943-175-02	2 in 1 CARTON	05/16/2014	
1		12 in 1 BLISTER PACK; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/16/2014	

Labeler - DISCOUNT DRUG MART (047741335)

Revised: 9/2020

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