

COLD MULTI-SYMPTOM NIGHT-TIME- acetaminophen, chlorpheniramine maleate, dextromethorphan hbr and phenylephrine hci tablet
Allegiant Health

Drug Facts

Active ingredient

Acetaminophen 325 mg
Chlorpheniramine maleate 2 mg
Dextromethorphan HBr 10 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer
Antihistamine
Cough suppressant
Nasal decongestant

Uses

temporarily relieves these common cold/flu symptoms:

- minor aches and pains
- headache
- sore throat
- nasal congestion
- cough
- sneezing and runny nose
- sinus congestion and pressure
- helps clear nasal passages
- relieves cough to help you sleep
- temporarily reduces fever

Warnings

Liver warning/Allergy alert

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

- with other drugs containing acetaminophen

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 immediately

Sore throat warning

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, 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
- taking sedatives or tranquilizers

When using this product

do not exceed recommended dosage.

- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occurs
- 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 accidental overdose, contact a doctor or Poison Control Center (1-800-222-1222) immediately. Taking more than the recommended dose (overdose) may cause liver damage. 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 Warnings)

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 a total of 10 caplets in 24 hours

Children under 12 years: ask a doctor

Other Information

- store at room temperature 20°- 25°C (68°- 77°F)
- **do not use if blister is torn or open**

Inactive Ingredients

corn starch, crospovidone, croscarmellose sodium, FD&C blue #1 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, polyethylene glycol, silicon dioxide, stearic acid, titanium dioxide

May contain: FD&C lake black

Questions or comments?

Call toll free 1-888-952-0050 Monday through Friday

Package/Label Principal Display Panel

Drug Facts (continued)

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 in more than 4,000 mg of acetaminophen in 24 hours in with other drugs containing acetaminophen in 3 or more alcoholic drinks every day while using this product.
Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include: in skin reddening in blisters in 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: in with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. in 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. in if you have ever had an allergic reaction to this product or any of its ingredients.

Ask a doctor before use if you have: in liver disease in heart disease in high blood pressure in thyroid disease in diabetes in trouble urinating due to an enlarged prostate gland in persistent or chronic cough such as occurs with smoking, asthma or emphysema. in cough that occurs with too much phlegm (mucus) in a breathing problem such as emphysema or chronic bronchitis in glaucoma.

Ask a doctor or pharmacist before use if you are: in taking the

Drug Facts (continued)

blood thinning drug warfarin in taking sedatives or tranquilizers. When using this product, in do not exceed maximum in excitability may occur, especially in children. in marked may occur in alcohol, sedatives and tranquilizers may in drowsiness in avoid alcoholic drinks in be careful when motor vehicle or operating machinery.

Stop use and ask a doctor if: in nervousness, dizziness, sleeplessness occur in pain, nasal congestion or cough g or lasts more than 7 days in fever gets worse or lasts more days in redness or swelling is present in new symptoms in cough comes back or occurs with rash or headache. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional. Keep out of reach of children. Overdose warnings: In case overdose, get medical help or contact a Poison Control Center away (1-800-222-1222). Quick medical attention is critical as well as for children even if you do not notice any signs or symptoms.

Directions:
in do not take more than directed (see overdose warning)
Adults and children 12 years and older: in swallow whole; do not crush, chew and older: in do not take more than 10 caplets in 24 hours.
Children under 12 years: in ask a doctor.

Other information: in store at room temperature (59°–77°F) in do not use if blister unit is torn or open.

Drug Facts (continued)

Inactive ingredients: corn starch, croscopolidone, croscarmellose sodium, FD&C Blue #1 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polydioxane, pregelatinized starch, polyethylene glycol, silicon dioxide, stearic acid, titanium dioxide. May contain: FD&C lake black.

Drug Facts (continued)

Questions or comments?
 Call 1-888-952-0050 Monday through Friday.

Drug Facts

Active ingredient (in each caplet)

Chlorpheniramine maleate 2mg.....	Antihistamine
Dextromethorphan HBr 10mg.....	Cough suppressant
Phenylephrine HCl 5mg.....	Nasal decongestant

Drug Facts (continued)

Uses: for the temporary relief of the following cold/flu symptoms: in minor aches and pains in headache in sore throat in nasal congestion in cough in sinus congestion and pressure in and runny nose in helps clear nasal passages in relieves help you sleep in temporarily reduces fever.

Cold Multi-symptom

COLD MULTI-SYMPATOM NIGHT-TIME

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr and phenylephrine hci tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-319
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	
CROSPVIDONE (UNII: 2S7830E561)	

Product Characteristics

Color	blue	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	AZ 319
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-319-86	12 in 1 BLISTER PACK; Type 0: Not a Combination Product	12/23/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	12/23/2014	

Labeler - Allegiant Health (079501930)

Revised: 12/2018

Allegiant Health