

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

Allegiant Health

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.

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. Severe liver damage may occur if you take:

- more than 12 caplets in 24 hours, which is the maximum daily amount
- 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 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 products 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 drugs. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist.

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

When using this product

do not use exceed recommended dosage

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

If pregnant or breast-feeding, ask a health professional before use

Keep Out of Reach of Children

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 **Warnings**)

Adults and children 12 years and over:

- take 2 caplets every 4 hours
- do not take more than a total of 12 caplets in 24 hours

Children under 12 years: Do not use this adult product in children under 12 years of age. This will provide more than recommended dose (overdose) and may cause liver damage

Other Information

- store between 15-30°C (59-86°F)
- **do not use if blister is torn or open**

Inactive Ingredients

colloidal silicone dioxide, cornstarch, croscarmellose sodium, FD&C blue #1, FD&C lake black, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, stearic acid, titanium dioxide

Questions or comments?

Call toll free 1-888-952-0050

Package/Label Principal Display Panel

Cold Multi-Symptom NT

COLD MULTI-SYMPTOM NIGHT-TIME

acetaminophen,chlorpheniramine maleate, dextromethorphan hbr and phenylephrine hci tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69 168 -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)	
CROSCARMELLOSE 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)	

Product Characteristics			
Color	BLUE	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	AZ319
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69 168 -319 -86	12 in 1 BLISTER PACK; Type 0: Not a Combination Product	12/23/20 14	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	12/23/20 14	

Labeler - Allegiant Health (079501930)

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