

NIGHTTIME COLD AND FLU RELIEF- acetaminophen capsule

Allegiant Health

418-Nighttime Cold and Flu Relief

Active ingredient(s)

Acetaminophen 325mg

Dextromethorphan HBr 15mg

Doxylamine succinate 6.25mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Use(s)

temporarily relieves common cold and flu symptoms:

- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever
- runny nose and sneezing

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4 doses in 24 hours, which is the maximum daily amount for this product
- 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 drugs. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product
- to make a child sleep

Ask a doctor before use if

- liver disease
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product

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

Stop use and ask a doctor if

- pain 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.

Pregnancy/Breastfeeding

ask a health professional before use.

Keep out of reach of children

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children, even if you do not notice any signs or symptoms.

Directions

- take only as directed
- do not exceed 4 doses per 24 hours
- Adults and children 12 years and over: 2 softgels with water every 6 hours
- Children 4 to under 12 years of age: ask a doctor
- Children under 4 years of age: do not use

Other information

Do not use if blister unit is torn or open

Storage

- store at room temperature 20-25 °C (68-77° F)

Inactive ingredients

D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution
May contain: sorbitol 70% solution, titanium dioxide, white edible ink

Questions

Call 1-888-952-0050 Monday through Friday

Principal Display Panel

C28-AC1624

Drug Facts

Active Ingredients (In each softgel)	Purpose
Dextromethorphan HBr 15mg	Cough suppressant
Doxylamine succinate 6.25mg	Antihistamine

Uses: temporarily relieves common cold and flu symptoms:
 ■ cough due to minor throat and bronchial irritation
 ■ sore throat ■ headache ■ minor aches and pains ■ fever
 ■ runny nose and sneezing

Warnings:
Liver warnings: This product contains acetaminophen. Severe liver damage may occur if you take: ■ more than 4 doses in 24 hours, which is the maximum daily amount for this product ■ 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 redness ■ 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 drugs. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product. ■ to make a child sleep

Ask a doctor before use if you have: ■ liver disease ■ glaucoma ■ cough that occurs with too much phlegm (mucus) ■ a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema ■ trouble urinating due to an enlarged prostate gland

Drug Facts (continued)

Ask a doctor or pharmacist before use if you are:
 ■ taking sedatives or tranquilizers ■ taking the blood thinning drug warfarin

When using this product: ■ excitability may occur, especially in children ■ marked drowsiness may occur ■ avoid alcohol drink ■ be careful when driving a motor vehicle or operating machinery ■ alcohol, sedatives, and tranquilizers may increase drowsiness

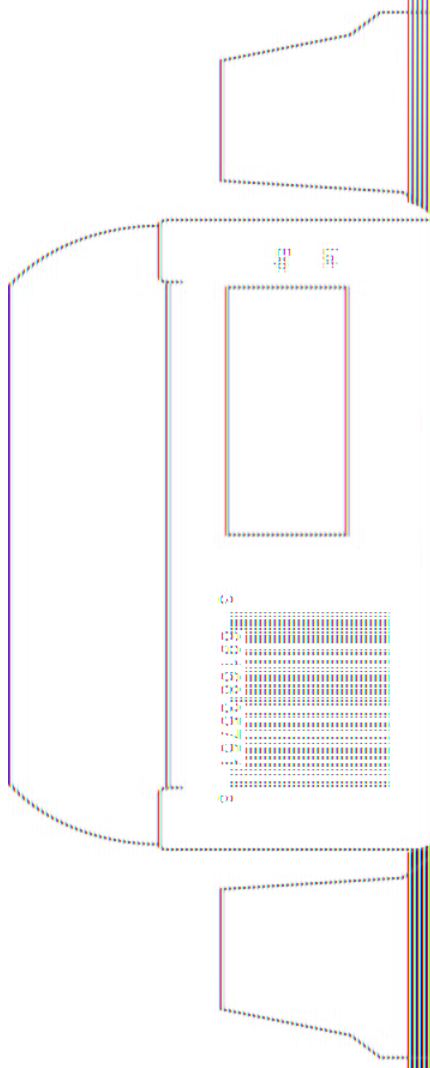
Stop use and ask a doctor if: ■ pain gets worse or lasts more than 7 days ■ fever gets worse or lasts more than 3 days ■ redness or swelling is present ■ new symptoms occur ■ cough comes back or occurs with rash or headache that last These could be signs of a serious condition.

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

Directions: ■ take only as directed ■ do not exceed 4 doses per 24 hours
 ■ Adults and children 12 years and over: 2 softgels with water every 6 hours
 ■ Children 4 to under 12 years of age: ask a doctor
 ■ Children under 4 years of age: do not use

Other information: ■ store at room temperature 20-25 °C (68-77° F) ■ do not use if blister unit is torn or open ■ You may report side effects to 1-888-952-0050

Inactive ingredients: D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution
 May contain: sorbitol 70% solution, titanium dioxide, white edible ink



HealthAzz® NIGHTTIME
 COLD & FLU RELIEF

Aches Fever
 Sore Throat
 Runny Nose
 Sneezing
 Cough

20 Softgels



See new warnings information
 Runny Nose
 Cough
 Sore Throat
 Sneezing
 Aches Fever

Acetaminophen/Dextromethorphan/Doxylamine
COLD & FLU RELIEF

NIGHTTIME

HealthAzz®
 Compare to active ingredients in
 other brands of Cold & Flu Relief

HealthAzz® NIGHTTIME
 COLD & FLU RELIEF

Nighttime Cold and Flu Relief

NIGHTTIME COLD AND FLU RELIEF

acetaminophen capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-418
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	

Product Characteristics

Color	green (Clear)	Score	no score
Shape	CAPSULE (Oblong)	Size	20mm
Flavor		Imprint Code	PC10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-418-29	8 in 1 BLISTER PACK; Type 0: Not a Combination Product	11/11/2020	
2	NDC:69168-418-51	20 in 1 BLISTER PACK; Type 0: Not a Combination Product	11/11/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	11/11/2020	

Labeler - Allegiant Health (079501930)

Revised: 11/2020

Allegiant Health