

DAYTIME COLD AND FLU- acetaminophen 325mg/ dextromethorphan hbr 10mg/ phenylephrine hcl 5mg capsule
Allegiant Health

417- Daytime Cold and Flu

Active ingredient(s)

Acetaminophen 325mg

Dextromethorphan HBr 10mg

Phenylephrine HCl 5mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Use(s)

temporarily relieves common cold and flu symptoms: ■ nasal congestion ■ cough due to minor throat and bronchial irritation ■ sore throat ■ headache ■ minor aches and pains ■ fever

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

Sore throat warning: If sore throat is severe, lasts for more than 2 days, occurs with or followed by fever, headache, rash, nausea, or vomiting, see 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.

Ask a doctor before use if

■ 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

taking the blood thinning drug warfarin.

When using this product

do not use more than directed

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- symptoms get worse or last more than 5 days (children) or 7 days (adults)
- fever gets worse or lasts more than 3 days and redness or swelling is present
- new symptoms occurs
- 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

Taking more than directed can cause serious health problems. 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 4 hours
- Children 4 to under 12 years: ask a doctor
- Children under 4 years: 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

FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, white edible ink

Questions

Call 1-888-952-0050 Monday through Friday

Principal Display Panel

Drug Facts

Active ingredients (in each softgel)

Active ingredient	Purpose
Dextromethorphan HBr 10mg	Cough suppressant
Pseudoephedrine HCl 5mg	Nasal decongestant

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

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, lasts 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.
 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

Drug Facts (continued)
 ■ cough that occurs with too much phlegm (mucus) ■ persistent or chronic cough as occurs with smoking, asthma, or emphysema
 Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.
 When using this product do not use more than directed.
 Stop use and ask a doctor if ■ you get nervous, dizzy or sleepless ■ pain, nasal congestion or cough get worse or last 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. 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 of age and older: 2 softgels with water every 4 hours. ■ Children 4 to under 12 years: ask a doctor ■ Children under 4 years: 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: FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution
 May contain: titanium dioxide, white edible ink

Hedmaz DAYTIME
 COLD & FLU RELIEF

Acetaminophen/Dextromethorphan HBr/Pseudoephedrine HCl
 Non-drowsy
 DAYTIME
 COLD & FLU RELIEF

20 Softgels

Fever
 Sore Throat
 Sneezing
 Runny Nose
 Cough

69108 35613

Compare to active ingredients in other drugs and a Flu-Cough™



Daytime Cold and Flu

DAYTIME COLD AND FLU

acetaminophen 325mg/ dextromethorphan hbr 10mg/ phenylephrine hcl 5mg capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-417
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	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	

Product Characteristics

Color	orange	Score	no score
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Shape	CAPSULE	Size	21mm
Flavor		Imprint Code	PC9
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-417-51	2 in 1 CARTON	11/11/2020	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:69168-417-29	8 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