

# **DAYTIME AND NIGHTTIME COLD AND FLU KIT- daytime and nighttime cold and flu kit**

**Allegiant Health**

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## **474 418 - Daytime and Nighttime Cold and Flu Relief**

### **Active ingredient(s)**

#### **DAYTIME ONLY**

Acetaminophen 325mg

Dextromethorphan HBr 10mg

#### **NIGHTTIME ONLY**

Acetaminophen 325mg

Dextromethorphan HBr 15mg

Doxylamine succinate 6.25mg

### **Purpose**

#### **DAYTIME ONLY**

Pain reliever/fever reducer

Cough suppressant

#### **NIGHTTIME ONLY**

Pain reliever/fever reducer

Cough suppressant

Antihistamine

### **Use(s)**

#### **DAYTIME ONLY**

temporarily relieves these symptoms due to a cold or flu:

- cough
- sore throat
- headache
- minor aches and pains
- temporarily reduces fever

#### **NIGHTTIME ONLY**

temporarily relieves common cold/flu symptoms:

- cough due to minor throat & bronchial irritation

- sore throat
- headache
- minor aches & pains
- fever
- runny nose & sneezing

## **Warnings**

### **DAYTIME**

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

- more than 10 softgels 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

### **NIGHTTIME**

**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

### **DAYTIME AND NIGHTTIME**

**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, occurs with or is followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

## **Do not use if you have**

### **DAYTIME ONLY**

- 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
- in children under 12 years of age

## **NIGHTTIME ONLY**

- 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.
- to make a child sleep

## **Ask a doctor before use if you**

### **DAYTIME ONLY**

- liver disease • heart disease • thyroid disease • diabetes • high blood pressure
- trouble urinating due to an enlarged prostate gland • cough that occurs with too much phlegm (mucus) • persistent or chronic cough as occurs with smoking, asthma, or emphysema

### **NIGHTTIME ONLY**

- 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 enlarged prostate gland

## **Ask a doctor or pharmacist before use if**

### **DAYTIME ONLY**

taking the blood thinning drug warfarin.

### **NIGHTTIME ONLY**

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

## **When using this product**

### **DAYTIME ONLY**

do not exceed recommended dosage.

### **NIGHTTIME ONLY**

- do not use more than directed
- excitability may occur, especially in children
- marked drowsiness may occur • avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives & tranquilizers may increase drowsiness

## **Stop use and ask a doctor if**

### **DAYTIME ONLY**

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occurs
  - pain, cough gets 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.

### **NIGHTTIME ONLY**

- pain 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 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**

#### **DAYTIME ONLY**

- Take only as directed
- Do not exceed 4 doses in 24hours

**Adults and children 12 yrs & over:** 2 softgels with water every 4 hrs

**Children under 12 yrs:** ask a doctor

**Children under 4 yrs:** do not use

#### **NIGHTTIME ONLY**

- Take only as directed
- Do not exceed 4 doses in 24hours

**Adults and children 12 yrs & over:** 2 softgels with water every 6 hrs

**Children 4 to under 12 yrs:** ask a doctor

**Children under 4 yrs:** do not use

### **Other information**

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



# DAYTIME AND NIGHTTIME COLD AND FLU KIT

daytime and nighttime cold and flu kit kit

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69168-013
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-013-15	1 in 1 CARTON; Type 0: Not a Combination Product	03/06/2026	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 BLISTER PACK	24
Part 2	1 BLISTER PACK	12

## Part 1 of 2

### DAYTIME COLD AND FLU

daytime cold and flu capsule, liquid filled

## Product Information

<b>Item Code (Source)</b>	NDC:69168-474
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<b>Route of Administration</b>	ORAL
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## 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

## 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 400 (UNII: B697894SGQ)	

<b>POVIDONE K12</b> (UNII: 333AG72FWJ)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	21mm
<b>Flavor</b>		<b>Imprint Code</b>	P41
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-474-93	2 in 1 CARTON		
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	03/06/2026	

## Part 2 of 2

### NIGHTTIME COLD AND FLU RELIEF

acetaminophen capsule

### Product Information

<b>Item Code (Source)</b>	NDC:69168-418
<b>Route of Administration</b>	ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

## Product Characteristics

<b>Color</b>	green (Clear)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (OBLONG)	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	PC10
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-418-86	1 in 1 CARTON		
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	03/06/2026	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	03/06/2026	

**Labeler** - Allegiant Health (079501930)