DAYTIME NIGHTTIME COLD AND FLU RELIEF COMBO PACK- daytime nighttime cold and flu
Allegiant Health

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438 - Daytime Nighttime Cold and Flu

Active ingredient(s)

DAYTIME ONLY

Acetaminophen 325mg
Dextromethorphan HBr 10mg
Phenylephrine HCl 5mg

NIGHTTIME ONLY

Acetaminophen 325mg
Dextromethorphan HBr 15mg
Doxylamine succinate 6.25mg

Purpose

DAYTIME ONLY

Pain reliever/fever reducer
Cough suppressant
Nasal decongestant

NIGHTTIME ONLY

Pain reliever/fever reducer
Cough suppressant
Antihistamine

Use(s)

DAYTIME ONLY

temporarily relieves common cold/flu symptoms: • nasal congestion • cough due to minor throat & bronchial irritation • sore throat • headache • minor aches & pains • 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 AND NIGHTTIME

Liver warning: This product contains acetaminophen.
Severe liver damage may occur if you take:
• more than 4 doses in 24 hrs, 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, occurs with or is followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

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.

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 have

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 use more than directed

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

• 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
• 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.

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

DAYTIME ONLY

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

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

children 4 to 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 24 hrs

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)
- do not use if blister unit is torn or open

Inactive ingredients

DAYTIME ONLY

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

NIGHTTIME ONLY

D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, white edible ink

Questions

Questions or comments?

Call 1-888-952-0050 Monday through Friday 9AM - 5PM

Principal Display Panel

Day Time/Nighttime Cold and Flu

DAYTIME NIGHTTIME COLD AND FLU RELIEF COMBO PACK

daytime nighttime cold and flu kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69168-438

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-438-15	1 in 1 CARTON; Type 0: Not a Combination Product	05/20/2022	

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

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

Product Information

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: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-	2 in 1 CARTON		

1	417-93	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	05/20/2022	

Part 2 of 2

NIGHTTIME COLD AND FLU RELIEF

acetaminophen capsule

Product Information

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: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	

Product Characteristics

Color	green	**Score**	no score
Shape	CAPSULE	**Size**	20mm
Flavor		**Imprint Code**	PC10

Contains	

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	05/20/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	05/20/2022	

Labeler - Allegiant Health (079501930)

Revised: 5/2022 Allegiant Health