NUVICARE DAYTIME AND NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, doxylamine succinate
NUVICARE LLC

Nuvicare DayTime and NightTime Cold and Flu Softgel Combo Pack

Drug Facts

Active ingredients

Active ingredients in DayTime (in each softgel)

Acetaminophen 325mg

Dextromethorphan HBr 10mg

Phenylephrine HCl 5mg

Active ingredients in NightTime (in each softgel)

Acetaminophen 325mg

Dextromethorphan HBr 15mg

Doxylamine Succinate 6.25 mg

Purpose

DayTime

Acetaminophen 325mg.....Pain reliever/fever reducer
Dextromethorphan HBr 10mg..... Cough suppressant
Phenylephrine HCl 5mg ..... Nasal decongestant

NightTime

Acetaminophen 325mg.....Pain reliever/fever reducer
Dextromethorphan HBr 15mg..... Cough suppressant
Doxylamine succinate 6.25 mg ..... Antihistamine

Uses:

temporarily relieves common cold/flu symptoms:

■ nasal congestion **(DayTime Only)**

■ cough due to minor throat & bronchial irritation

■ sore throat

■ headache

■ minor aches & pains

■ fever

■ Runny nose and sneezing **(NightTime only)**

Warning

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: acetamenophen may cause severe skin recations. Symptoms may include:

■ skin reddening ■ blisters ■ rash. if a skin reactions 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 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 **(NightTime Only).**

Ask a doctor before use if you have

■ liver disease

■ Glaucoma **(NightTime Only)**

■ cough that occurs with too much phlegm (mucus)

■ trouble urinating due to enlarged prostate gland

■ a breathing problem, persistent or chronic cough as occurs with smoking, asthma, or emphysema and **(NightTime Only)** chronic Bronchitis

■ heart disease

■ diabetes **(DayTime Only)**

■ thyroid disease **(DayTime Only)**

■ high blood pressure **(DayTime Only)**

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers **(NightTime Only)**
- taking the blood thinning drug warfarin

When using this product-do not use more than directed.In addition when using NightTime:

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

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless **(DayTime Only)**
- pain, cough or nasal congestion **(DayTime only)** may 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 care professional before use.

Keep out of reach of children.

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

Directions

■ take only as directed- see **OVERDOSE WARNING**

■ do not exceed 8 softgels per 24 hrs.

■ Take softgels with water

	DayTime	**NightTime**
Adults and children age 12 yrs and over	2 softgels every 4 hrs.	2 softgels every 6 hrs.
Children 4 to under 12 yrs	ask a doctor	ask a doctor
Children under 4 yrs	do not use	do not use

Read each label carefully before taking Daytime and Nighttime products.

Other information

■ store between 15-30°C (59-86 °F)

■ avoid excessive heat, cold and humidity

Inactive ingredients

(Daytime)- Polyethylene glycol-400, Propylene glycol, Povidone K-30, Purified water, Gelatin, Glycerol, Sorbitol sorbitan solution,FD&C Red No. 40, FD&C Yellow No. 6.

(Nighttime)- Polyethylene glycol-400, Propylene glycol, Povidone K-30, Purified water, Gelatin, Glycerin, Sorbitol sorbitan solution,D&C Yellow No. 10, FD&C Blue No. 1.

Questions or Comments?

Call 1 (718) 337-8733 or email: support@nuvicare.com

NUVICARE DAYTIME AND NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, doxylamine succinate kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:84324-025

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:84324-025-01	1 in 1 CARTON; Type 1: Convenience Kit of Co-Package	06/09/2025	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BLISTER PACK	6
Part 2	1 BLISTER PACK	6

Part 1 of 2

NUVICARE DAYTIME COLD AND FLU SOFTGEL

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled

Product Information	
Item Code (Source)	NDC:84324-023
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 (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics			
Color	red	**Score**	no score
Shape	capsule (Oblong)	**Size**	21mm
Flavor		**Imprint Code**	DL01
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		6 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	06/09/2025	

Part 2 of 2

NUVICARE NIGHTTIME COLD AND FLU SOFTGEL

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

Product Information	
Item Code (Source)	NDC:84324-024
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)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	green	**Score**	no score
Shape	capsule (Oblong)	**Size**	21mm
Flavor		**Imprint Code**	NL01
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		6 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	06/09/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/09/2025	

Labeler - NUVICARE LLC (119257565)

Registrant - NUVICARE LLC (119257565)

Revised: 6/2025 NUVICARE LLC