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

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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 HCI 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:

 $\blacksquare$  more than 4 doses in 24 hrs, which is the maximum daily amount for this product  $\blacksquare$  with other drugs containing acetaminophen  $\blacksquare$  3 or more alcoholic drinks every day while using this product.

**Allergy Alert:** acetamenophen may cause severe skin recations. Symptoms may include:

skin reddening  $\blacksquare$  blisters  $\blacksquare$  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 Infor							
Product Type	HUMAN	OTC DRUG	ltem Code	(Sourc	e)	NDC:84324	-025
Packaging				Mark	ating Start	Marka	ting End
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Quantity of Pa	arts						
Part #	Package C	Quantity		Tot	al Product Q	uantity	
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Part 2 1 BLISTER	РАСК		6				
Part 1 of 2							
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			Ingredi	ent Name		Strength
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FD&	C BLUE NO	. 1 (UNII	: H3R47K3TBD)			
GEL	ATIN (UNII: 2	2G86QN3	327L)			
POL	YETHYLENE		DL, UNSPECIFIED (UNI	I: 3WJQ0SDW1A)		
ΡΟν	IDONE (UNI	l: FZ 989	GH94E)			
PRO	PYLENE GL	YCOL (L	JNII: 6DC9Q167V3)			
WAT	TER (UNII: 05	9QF0KO	0R)			
SOR	BITOL (UNII	: 506T60	)A25R)			
SOR	BITAN (UNII	: 609210	CV9RU)			
Pro	duct Cha	aracte	ristics			
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Labeler - NUVICARE LLC (119257565)

## Registrant - NUVICARE LLC (119257565)

Revised: 6/2025