

**NUVICARE NIGHTTIME COLD AND FLU SOFTGEL- acetaminophen,
dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled
NUVICARE LLC**

**Nuvicare NightTime Cold and Flu Softgel (Acetaminophen 325mg,
Dextromethorphan HBr 15mg, Doxylamine succinate 6.25 mg)**

Drug Facts

Active ingredients (in each softgel)

Acetaminophen 325mg

Dextromethorphan HBr 15mg

Doxylamine succinate 6.25 mg

Purpose

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

Uses:

temporarily relieves these common cold/flu symptoms:

- minor aches & pains
- headache
- sore throat
- fever
- Runny nose and sneezing
- cough due to minor throat & bronchial irritation

Warning

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

- more than 8 softgels in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks everyday 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:

- 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.
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist

Ask a doctor before use if you have

- liver disease
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that last 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 you are

- taking the blood thinning drug warfarin
- taking sedative or tranquilizers.

When using this product

- do not exceed recommended dosage.
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedative and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- pain or cough get worse or lasts more than 7 days
- new symptoms occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- 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.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as 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

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

Other information

- store between 15-30°C (59 to 86 °F)
- avoid excessive heat

Inactive ingredients

Polyethylene Glycol400, Propylene Glycol, Povidone (PVP K-30),Purified water, Gelatin, Glycerin, Sorbitol Sorbitan solution, FD & C Blue No. 1, D &C Yellow No.10

Questions or Comments?

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

Distributed by: Nuvicare LLC, Brooklyn, NY 11211, USA



NUVICARE NIGHTTIME COLD AND FLU SOFTGEL

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84324-019
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
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE (UNII: FZ989GH94E)	
Gelatin (UNII: 2G86QN327L)	
Sorbitol (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

Product Characteristics

Color	green	Score	no score
Shape	capsule (Oblong)	Size	19mm
Flavor		Imprint Code	SD15
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84324-019-01	1 in 1 CARTON	05/20/2025	
1		10 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	05/20/2025	

Labeler - NUVICARE LLC (119257565)

