

NIGHTTIME COLD AND FLU RELIEF - acetaminophen, dextromethorphan hydrobromide and doxylamine succinate capsule
Aurohealth LLC

NIGHTTIME COLD AND FLU RELIEF

Drug Facts

Active ingredients (in each capsule)

Acetaminophen USP 325 mg
Dextromethorphan HBr USP 15 mg
Doxylamine succinate USP 6.25 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Antihistamine

Uses

temporarily relieves common cold/flu symptoms:

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

Warnings

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

- more than 8 capsules 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

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, 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.

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 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 you are

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

When using this product

- **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, and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- 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 breast-feeding,

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 right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- take only as directed
- do not exceed 8 capsules per 24 hrs

adults & children 12 yrs & over	2 capsules 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

Inactive ingredients

D&C Yellow No. 10, gelatin, glycerin, Neelicert FD&C Blue No. 1, polyethylene glycol, povidone, propylene glycol, purified water, shellac glaze, sorbitol sorbitan solution, titanium dioxide

Questions or comments?

call **1-855-274-4122**

Distributed by:

AUROHEALTH LLC

279 Princeton-Hightstown Road

East Windsor, NJ 08520

Made in India

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - (24 Capsules Bottle)

AUROHEALTH

NDC 58602-769-78

Compare to the active ingredients
in VICKS[®] NyQuil[®] Cold & Flu
Nighttime Relief LiquiCaps^{®*}

**Nighttime Relief
Cold & Flu
Acetaminophen, Dextromethorphan HBr and
Doxylamine Succinate Capsules
325 mg/15 mg/6.25 mg**

- Headache, Fever, Sore Throat,
Minor Aches & Pains
- Sneezing, Runny Nose
- Cough

Actual Size

24

Capsules

LEBG9070

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NIGHTTIME COLD AND FLU RELIEF

acetaminophen, dextromethorphan hydrobromide and doxylamine succinate capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-769
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: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	GREEN	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	Q07
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-769-78	3 in 1 CARTON	06/29/2024	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:58602-769-79	1 in 1 CARTON	06/29/2024	
2		8 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	06/29/2024	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(58602-769) , MANUFACTURE(58602-769)