

LIDL NIGHTYIME COLD AND FLU RELIEF- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

Lidl US LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

LIDL NIGHTTIME COLD AND FLU RELIEF

Active ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

Purpose

Pain reliever/fever reducer

Cough Suppressant

Antihistamine

Uses

temporarily relieves common cold/flu symptoms:

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

Warnings

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

- more than 4 doses in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily 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 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 product 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

- 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 an 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
- 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

- 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.

Overdose warning: Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away at 1-800-222-1222. Quick medical attention is critical for adults & children, even if you do not notice any signs or symptoms.

Directions

- take only as directed- see Overdose warning
- do not exceed 4 doses in 24 hours

adults and children 12 years and over	2 softgels with water every 6 hours
children 4 to under 12 years	ask a doctor
children under 4 years	do not use

Other information

- store at room temperature

Inactive ingredients

D&C yellow No. 10, FD&C Blue No. 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol, sorbitan, titanium dioxide.

Questions or comments?

1-844-656-5151

Principal Display Panel

*Compare to the active ingredients in Vicks[®] NyQuil[®] Cold & Flu liquicaps[®]

NDC 71141-142-32

RELIEVES

Headache

Fever & Sore throat

Minor aches & pains

Sneezing

Runny Nose

Cough

Nighttime Cold & Flue RELIEF

Acetaminophen 325 mg Pain reliever/Fever reducer

Dextromethorphan HBr 15 mg Cough suppressant

Doxylamine succinate 6.25 mg Antihistamine

24 Softgels

For ages 12 years and overs

*This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks[®] Nyquil[®]

Cold & Flu LiquiCaps®

DISTRIBUTED BY

Lidl US, LLC

3500 S. Clark Street

Arlington, VA 22202

QUESTIONS?

1-844-656-5151

www.lidl.com

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

TAMPER EVIDENT: This package is safety sealed & child resistant. Use only if blisters are intact. If difficult to open, use scissors.

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: V9B19B5YI2) (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: HBR47K3TBD)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	GREEN	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	RP062
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71141-142-32	24 in 1 CARTON	04/17/2019	
1		1 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 final	part341	04/17/2019	

Labeler - Lidl US LLC (079389709)