NIGHT-TIME COLD AND FLU RELIEF- acetaminophen, doxylamine succinate, dextromethorphan hbr capsule, liquid filled HealthLife of USA

Night-Time Cold & Flu Relief

Active ingredients (in each Softgels)

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, lasts 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

- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drink
- 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. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Direction

- take only as directed
- do not exceed 4 doses per 24 hours

adults & children 12 yrs & over	2 softgels 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.
- TAMPER EVIDENT: This package is safety sealed & child resistant. Use only if blisters are intact. If difficult to open, use scissors.
- KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Inactive ingredients

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

Questions or comments?

1-844-832-1138

M-F 9am-5pm EST

Distributed by:

Health life of USA LLC Rahway, NJ 07065 www.healthlifeus.com

*This product is not manufactured or distributed by Procter & Gamble, Distributor of Vicks Nyquil $^{\circledR}$

PACKAGE LABEL

NDC 69517-161-10

10 Softgels

Night-Time Cold & Flu Relief

Acetaminophen, Doxylamine Succinate, Dextromethorphan HBr

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

*Compare to the active ingredients in Vicks Nyquil $^{ ext{@}}$



HealthLife Night-Time

Cold & FLU

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Drug Facts (Confinued)

POWERFUL Nighttime RELIEF



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NIGHT-TIME COLD AND FLU RELIEF

acetaminophen, doxylamine succinate, dextromethorphan hbr capsule, liquid filled

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69517-161

Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	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		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
GELATIN (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
POVIDONE K30 (UNII: U725QWY32X)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SORBITOL (UNII: 506T60A25R)			
METHYLPARABEN (UNII: A2I8C7HI9T)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			

Product Characteristics				
Color	green	Score	no score	
Shape	CAPSULE	Size	21mm	
Flavor		Imprint Code	SN3	
Contains				

Packaging

	#	# Item Code Package Description		Marketing Start Date	Marketing End Date
	1	NDC:69517- 161-10	1 in 1 CARTON	04/04/2023	
l	1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information					
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M012	04/04/2023			

Labeler - HealthLife of USA (079656178)

Registrant - HealthLife of USA (079656178)

Revised: 10/2023 HealthLife of USA