

**NIGHTTIME COLD AND FLU RELIEF- acetaminophen, dextromethorphan,
doxylamine capsule, liquid filled
HealthLife of USA**

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.

NightTime Cold and Flu Relief Acetaminophen, Dextromethorphan and Doxylamine

Active Ingredient

(in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Doxylamine Succinate 6.25 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Uses

temporarily relieves common cold and 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 every day while using this product

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 products 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 drugs. 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 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 exceed recommended dosage**
- 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 last 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.

Keep out of reach of children.

If pregnant or breast-feeding, ask a health professional before use.

Overdose warning: Taking more than recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt 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 – see overdose warning**
- **do not exceed 4 doses per 24 hours**
- **Adults and children 12 years and over:** 2 softgels with water every 4 hours
- **children 4 to under 12 years:** ask a doctor
- **Children under 4 years:** do not use

Other Information

- store at room temperature.
- read all product information before using.
- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.**

Inactive Ingredients

D&C Yellow No.10, FD&C Blue No. 1, Gelatin, Glycerin, Poyethylene Glycol, Povidone, Propylene Glycol, Purified Water, Sorbitol, Titanium dioxide

Questions or Comments

1-844-832-1138 (Mon-Fri 9AM-5PM EST) or www.healthlifeofusa.com

PACKAGE LABEL

***This product is not manufactured or distributed by the Procter & Gamble Company. Vicks®, NyQuil®, and LiquiCaps® are registered trademark of the Procter & Gamble Company.**

NDC: 69517-103-16 16 softgels

NDC: 69517-103-10 10 softgels

HealthLife Night-Time Cold & FLU

NDC 69517-103-110

POWERFUL Nighttime RELIEF

HealthLife

Night-Time

COLD & FLU

Nighttime Relief

Acetaminophen, Doxylamine Succinate, Dextromethorphan HBr

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

10 Softgels

**Compare to the active ingredients in Vicks Nyquil®*

Parents: www.kidprescriptionadvice.org

Drug Facts (Continued)
 Questions? 1-844-832-1138
 Distributed by: Health Life of USA, LLC
 Rahway, NJ 07065
www.healthlifeofusa.com

NO VARNISH AREA

Lot. No.:
Exp. Date:

Questions or comments? 1-844-832-1138 M-F 9am-5pm EST

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

This product is not manufactured or distributed by Procter & Gamble, Distributor of Vicks Nyquil®

Drug Facts (continued)
Directions
 • 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

Drug Facts (continued)
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 solution, titanium dioxide

Drug Facts

Active ingredients (in each Softgels)	Purpose
Acetaminophen 325 mg	Pain reliever/Fever reducer
Dextromethorphan HBr 15 mg	Cough suppressant
Doxylamine succinate 6.25 mg	Antihistamine

Uses temporarily relieves common cold/flu symptoms:

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

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Warnings

Liver warning: This product contains acetaminophen.

Severe liver damage may occur if you take

- more than 4 doses in 24 hrs, 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
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NIGHTTIME COLD AND FLU RELIEF

acetaminophen, dextromethorphan, doxylamine capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69517-103
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	10 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (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: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	GREEN	Score	no score
Shape	CAPSULE	Size	22mm
Flavor		Imprint Code	215
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69517-103-16	16 in 1 BOTTLE; Type 0: Not a Combination Product	08/26/2015	
2	NDC:69517-103-10	1 in 1 CARTON	06/09/2017	
2		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 final	part341	08/26/2015	

Labeler - HealthLife of USA (079656178)

Registrant - HealthLife of USA (079656178)

Establishment

Name	Address	ID/FEI	Business Operations
Softech Pharma Pvt. Ltd		67711277	manufacture(69517-103)

Revised: 6/2017

HealthLife of USA