

**NIGHTTIME COLD AND FLU- acetaminophen, doxylamine succinate,
dextromethorphan hbr capsule, liquid filled
Health Pharma USA LLC**

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
children 4 to under 12 yrs
children under 4 yrs

2 softgels with water every 6 hrs
ask a doctor
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# 10, FD&C Blue #1, Gelatin, Glycerin, Polyethylene Glycol 400, Povidone K30, Propylene Glycol, Purified Water, Sorbitol Sorbitan Solution

Questions or comments?

1-844-832-1138

M-F 9am-5pm EST

Distributed by:

Health Pharma USA LLC
Rahway, NJ 07065
www.health-pharma.us

PACKAGE LABEL

Health Pharma
Compare to NyQuil®
LiquiCaps® active ingredients*

**Multi-Symptom
Nighttime
Cold & Flu**

Acetaminophen 325 mg
Pain Reliever/Fever Reducer

Dextromethorphan HBr 15 mg
Cough Suppressant

Doxylamine Succinate 6.25 mg
Antihistamine

SEE NEW WARNINGS
INFORMATION

50 SOFTGELS

Drug Facts

Active ingredients (in each softgel)

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

Warnings

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 6 grams (2,600 mg acetaminophen) in 24 hours. Severe liver damage may occur if you take more than the recommended dose. Do not take more than 24 hours of this product. Do not take acetaminophen for more than 3 to 4 days unless directed by a doctor. Do not take acetaminophen with any more alcoholic drinks every day while using this product. **Sore throat warning:** If sore throat is severe, lasts for more than 2 days, occurs with or is 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 your 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 ■ if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have: ■ liver disease ■ diabetes ■ a breathing problem such as emphysema or chronic bronchitis ■ persistent or chronic cough as occurs with smoking, asthma, or emphysema ■ trouble urinating due to an enlarged prostate gland ■ cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if you are: ■ taking sedative or tranquilizers ■ taking the blood thinning drug warfarin

When using this product: ■ excitability may occur, especially in children ■ be careful when driving or operating machinery ■ avoid alcoholic drinks ■ avoid alcohol ■ avoid grapefruit juice ■ avoid grapefruit or grapefruit products ■ avoid sedatives, and tranquilizers may increase drowsiness ■ may cause marked drowsiness

Stop use and ask a doctor: ■ you get nervous, dizzy or sleepless ■ pain or cough gets worse or lasts more than 7 days ■ fever gets worse or lasts more than 3 days ■ new symptoms develop ■ drowsiness 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 effects, including coma. If overdose warning label is printed at top of Control Center (1-800-222-1222) right side, check for medical help or contact Poison Control Center (1-800-222-1222) right away. Quick response attention is critical for adults & for children even if you do not notice any signs or symptoms.

Directions ■ take only as directed - see Liver warning ■ do not exceed 8 doses per 24 hours ■ adults and children 12 years of age and over: 2 softgels with water every 4 hrs ■ children 4 to under 12 years of age: ask a doctor ■ children under 4 years of age: do not use ■ when using other Daytime or Nighttime products, carefully read each label to insure correct dosing

Other information ■ store at controlled room temperature 20°-25° C (68°-77° F) ■ keep container tightly closed ■ TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Inactive ingredients D&C yellow# 10, FD&C Blue #1, Gelatin, Glycerin, Polyethylene Glycol 400, Povidone K30, Propylene Glycol, Purified Water, Sorbitol Sorbitan Solution

Questions or comments? Call toll free 1-844-832-1138 Monday through Friday, 9AM-5PM EST

NDC 71679-102-50

50 Softgels

Nighttime Cold & Flu

*This product is not manufactured or distributed by Procter & Gamble, the distributor of NyQuil® LiquiCaps®



3 71679 10250 1

Acetaminophen, Doxylamine Succinate, Dextromethorphan HBr

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

***Compare to the active ingredients in LiquiCaps®**

NIGHTTIME COLD AND FLU				
acetaminophen, doxylamine succinate, dextromethorphan hbr capsule, liquid filled				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71679-102	
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	
FD&C RED NO. 40 (UNII: WZB9127XOA)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
GELATIN (UNII: 2G86QN327L)				
GLYCEROL FORMAL (UNII: 3L7GR2604E)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
POVIDONE K30 (UNII: U725QWY32X)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SORBITOL (UNII: 506T60A25R)				
Product Characteristics				
Color	green	Score	no score	
Shape	CAPSULE	Size	21mm	
Flavor		Imprint Code	CF01	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:71679-102-50	50 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2024	
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	12/20/2024	

Labeler - Health Pharma USA LLC (080804485)

Registrant - Health Pharma USA LLC (080804485)

Establishment

Name	Address	ID/FEI	Business Operations
OCEAN HEALTHCARE PVT. LTD.		873673519	manufacture(71679-102)

Revised: 12/2024

Health Pharma USA LLC