

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

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**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

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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

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**Other information**

- store at room temperature.

**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](http://www.health-Pharma.us)

**PACKAGE LABEL**

<b>“CF02” Imprint</b>	<b><u>Acetaminophen 325mg, Dextromethorphan Hydrobromide 15mg and Doxylamine Succinate 6.25mg Capsules</u></b>  <b>Each Soft Gelatin Capsule Contains:</b> Acetaminophen USP 325 mg Dextromethorphan Hydrobromide USP 15 mg Doxylamine Succinate USP 6.25 mg		
<b>Lot No.: OHS24253</b> <b>Mfg. Date: DEC. 2024</b> <b>Exp. Date: NOV. 2027</b>	<b>Shipper No.:</b> <b>Quantity: 2 x 1500 Capsules</b> <b>NDC No.: 71679-102-00</b>		
<b><u>WARNING: KEEP OUT OF REACH OF CHILDREN</u></b>			
STORE AT CONTROLLED ROOM TEMPERATURE OF 20° C – 25° C (68° F – 77° F) AVOID EXCESSIVE HEAT ABOVE 40°C (104°F). PROTECT FROM EXCESSIVE HEAT, LIGHT AND FREEZING.			
THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY. CONTENT SHOULD BE APPROVED, REPACKAGED IMMEDIATELY (9 MONTHS FROM MFG. DT) AND LABELED IN STRICT CONFORMANCE WITH THE FD&C ACT AND REGULATIONS THERE UNDER.			
<b>MANUFACTURED BY:</b> Ocean Healthcare Private Limited Survey No. 86/1-6, Orathur Village, Thiruporur Taluk, Chengalpattu District, Tamil Nadu – 6003 105. India. MFG. LIC. NO.: TN00003701 LABELLER CODE: 73751		<b>MANUFACTURED FOR:</b> HEALTH PHARMA USA LLC 1600 Hart Street Rahway, NJ 07065 Phone # (732) 433 5591 Email: hp@healthpharma.us	
<b><u>CAUTION: “FOR MANUFACTURING, PROCESSING OR REPACKING”</u></b>			

## NIGHTTIME COLD AND FLU

acetaminophen, doxylamine succinate, dextromethorphan hbr capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71679-102
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL SOLUTION</b> (UNII: 8KW3E207O2)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	

### Product Characteristics

<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	21mm
<b>Flavor</b>		<b>Imprint Code</b>	CF02
<b>Contains</b>			

### 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	12/20/2024
2	NDC:71679-102-00	2 in 1 BOX	01/07/2025	
2		1500 in 1 BAG; 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	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: 1/2025

Health Pharma USA LLC