

**MULTI-SYMPATOM NIGHTTIME COLD AND FLU RELIEF- acetaminophen,  
doxylamine succinate, dextromethorphan hbr capsule, liquid filled  
Advanced Rx LLC**

-----  
**Multi-Symptom Night-Time Cold and Flu Relief Softgels**

***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 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

**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 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 non-prescription).
- 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.
- 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
- 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 drinks
- 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 (1-800-222-1222) right away. Quick medical attention is critical for adults and 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

---

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

---

#### **Other information**

- store at room temperature.
- **DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED.**

#### ***Inactive ingredients***

D&C Yellow No10, FD&C Blue No 1, gelatin, glycerin, polyethylene glycol 400, povidone K30, propylene glycol, purified water, sorbitol sorbitan solution.

#### ***Questions?***

call toll-free **1-800-630-8895**

#### ***Distributed by:***

##### **Advanced Rx**

1942 NE 163rd St,  
North Miami Beach, FL 33162 U.S.A.

#### **PACKAGE LABEL**

##### **NDC 80513-316-50**

*\*Compare to the active ingredients in Vicks <sup>®</sup>NyQuil <sup>®</sup>Cold & Flu LiquiCaps <sup>®</sup>*

##### **50 Softgels**

##### **MULTI-SYMPTOM NIGHTTIME COLD & FLU RELIEF**

Acetaminophen,  
Dextromethorphan HBr,  
Doxylamine Succinate

- Pain Reliever
- Fever Reducer
- Cough Suppressant
- Antihistamine

\*This product is not manufactured or distributed by the owner of the registered

3  
80513-00060  
6



NDC 80513-316-50

Compare to the active ingredients in Vicks® NyQuil® Cold & Flu LiquiCaps®\*\*

**PUREGEN LABS**

# MULTI-SYMP TOM NIGHTTIME

## COLD & FLU RELIEF



**Acetaminophen**  
Dextromethorphan HBr  
Doxylamine Succinate

**50 SOFTGELS**

- PAIN RELIEVER
- FEVER REDUCER
- COUGH SUPPRESSANT
- ANTIHISTAMINE

**DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED**

**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 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

**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 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 non-prescription), 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. ■ if you have

**PEEL FOR DIRECTIONS**  
**LIFT HERE**

**Drug Facts (continued)**

ever had an allergic reaction to this product or any of its ingredients

**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 exceed recommended dosage ■ excitability may occur, especially in children ■ marked drowsiness may occur ■ avoid alcoholic drinks ■ 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 (1-800-222-1222) right away. Quick medical attention is critical for adults and for children even if you do not notice any signs or symptoms.

**Directions**

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

<b>adults and children 12 years and over</b>	take 2 softgels with water every 6 hours
<b>children 4 to under 12 years</b>	ask a doctor
<b>children under 4 years</b>	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 400, povidone K30, propylene glycol, purified water, sorbitol sorbitan solution.

**Questions?** call toll-free 1-800-630-8895

\*This product is not manufactured or distributed by the owner of the registered trademark Vicks® NyQuil® Cold & Flu LiquiCaps®

Distributed by:  
Advanced Rx  
1942 NE 163rd St  
North Miami Beach, FL 33162 U.S.A.

<b>MULTI-SYMP TOM NIGHTTIME COLD AND FLU RELIEF</b>			
acetaminophen, doxylamine succinate, dextromethorphan hbr capsule, liquid filled			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80513-316
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
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>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<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>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>SORBITOL SOLUTION</b> (UNII: 8KW3E207O2)	

## Product Characteristics

<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	OVAL	<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:80513-316-50	50 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2025	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	01/01/2025	

**Labeler** - Advanced Rx LLC (042795108)

## Establishment

Name	Address	ID/FEI	Business Operations
Ocean Healthcare Pvt Ltd		873673519	manufacture(80513-316)

Revised: 1/2025

Advanced Rx LLC