

**NIGHTTIME COLD AND FLU RELIEF SOFTGELS MULTI-SYMPTOM-  
acetaminophen, dextromethorphan hbr, doxylamine succinate capsule,  
gelatin coated  
Advanced Rx LLC**

*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.*

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**Advanced Rx - PUREGEN - MULTI-SYMPTOM NIGHTTIME COLD & FLU RELIEF  
(80513-302)**

**ACTIVE INGREDIENT (IN EACH SOFTGEL)**

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 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 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

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adults and children 12 years and over  
children 4 to under 12 years  
children under 4 years

take 2 softgels with water every 6 hours  
ask a doctor  
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, polysorbate, povidone, propylene glycol, purified water, sorbitol 70% solution, sorbitol sorbitan solution, titanium dioxide.

## QUESTIONS?

call toll-free 1-800-630-8895

**PUREGEN LABS**

NDC 80513-302-50

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

**MULTI-SYMP TOM**

**NIGHTTIME**

**COLD & FLU RELIEF**

**50**  
SOFTGELS

**Acetaminophen**  
Dextromethorphan HBr  
Doxylamine Succinate

- PAIN RELIEVER
- FEVER REDUCER
- COUGH SUPPRESSANT
- ANTIHISTAMINE

3  
80513  
00060  
6

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

## Drug Facts

### Active ingredients (in each softgel) 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 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

LIFT HERE

↓ PEEL FOR DIRECTIONS

G7560-050-106-0

### 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

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

### Other information

- store at room temperature

### Inactive ingredients

D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, polysorbate, povidone, propylene glycol, purified water, sorbitol 70% solution, sorbitol sorbitan solution, titanium dioxide.

**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.

## NIGHTTIME COLD AND FLU RELIEF SOFTGELS MULTI-SYMPTOM

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, gelatin coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80513-302
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<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
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

## Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN (UNII: 6O92ICV9RU)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POLAWAX POLYSORBATE (UNII: Q504PL8E0V)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GLYCERIN (UNII: PDC6A3C0OX)	
GELATIN TYPE B BOVINE (160 BLOOM) (UNII: 1T8387508X)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	

## Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	IS2
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80513-302-50	50 in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/24/2023	

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

Revised: 5/2023

Advanced Rx LLC