

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

**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

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

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

Acetaminophen
 Dextromethorphan HBr
 Doxylamine Succinate

50
 SOFTGELS

- 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 LiquidCaps®

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

NIGHTTIME COLD AND FLU RELIEF SOFTGELS MULTI-SYMPOM

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, gelatin coated

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
ACETAMINOPHEN (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 Drug	M012	04/24/2023	

Labeler - Advanced Rx LLC (042795108)

Revised: 9/2024

Advanced Rx LLC