

**DAYTIME COLD AND FLU RELIEF SOFTGELS NON-DROWSY- acetaminophen,  
dextromethorphan hbr, phenylephrine capsule, gelatin coated  
Advanced Rx LLC**

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**Advanced Rx - PUREGEN - NON-DROWSY DAYTIME COLD & FLU RELIEF  
(80513-301)**

**ACTIVE INGREDIENT (IN EACH SOFTGEL)**

Acetaminophen 325 mg  
Dextromethorphan HBr 10 mg  
Phenylephrine HCl 5 mg

**PURPOSE**

Pain reliever/fever reducer  
Cough suppressant  
Nasal decongestant

**USES**

Temporarily relieves common cold and flu symptoms:

- nasal congestion
- cough due to minor throat and bronchial irritation
- headache
- minor aches and pains
- fever
- sore throat

**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, 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 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
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough as occurs with smoking, asthma, or emphysema

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.

When using this product, do not use more than directed.

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- pain, nasal congestion or cough gets worse or last 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	take 2 softgels with water every 4 hours
children 4 to under 12 years	ask a doctor
children under 4 years	do not use

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## **OTHER INFORMATION**

- store at room temperature

## INACTIVE INGREDIENTS

FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, polysorbate, povidone, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide.

## QUESTIONS?

call toll-free 1-800-630-8895

**PUREGEN LABS**

NDC 80513-301-50  
Compare to the active ingredients in Vicks® DayQuil® Cold & Flu LiquiCaps®\*

**NON-DROWSY**  
**DAYTIME**  
**COLD & FLU RELIEF**

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80513  
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**Acetaminophen**  
Phenylephrine HCl  
Dextromethorphan HBr

- PAIN RELIEVER
- FEVER REDUCER
- COUGH SUPPRESSANT
- NASAL DECONGESTANT

**50**  
SOFTGELS

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

## Drug Facts

<b>Active ingredients</b> (in each softgel)	<b>Purpose</b>
Acetaminophen 325 mg.....	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg.....	Cough suppressant
Phenylephrine HCl 5 mg.....	Nasal decongestant

**Uses** Temporarily relieves common cold and flu symptoms:  
■ nasal congestion ■ cough due to minor throat and bronchial irritation ■ headache ■ minor aches and pains ■ fever ■ sore throat

## 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, 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 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

LIFT HERE

PEEL FOR DIRECTIONS

G7550-050-106-0

### Drug Facts (continued)

Ask a doctor before use if you have ■ liver disease ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland ■ cough that occurs with too much phlegm (mucus) ■ persistent or chronic cough as occurs with smoking, asthma, or emphysema

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.

When using this product, do not use more than directed.

Stop use and ask a doctor if ■ you get nervous, dizzy or sleepless ■ pain, nasal congestion or cough gets worse or last 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
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children under 4 years	do not use

### Other information

- store at room temperature

### Inactive ingredients

FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, polysorbate, povidone, propylene glycol, purified water, 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® DayQuil® Cold & Flu LiquiCape®

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

## DAYTIME COLD AND FLU RELIEF SOFTGELS NON-DROWSY

acetaminophen, dextromethorphan hbr, phenylephrine capsule, gelatin coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80513-301
<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	10 mg
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	5 mg
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	

<b>POLAWAX POLYSORBATE</b> (UNII: Q504PL8E0V)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GELATIN TYPE B BOVINE (160 BLOOM)</b> (UNII: 1T8387508X)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ05DW1A)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL SOLUTION</b> (UNII: 8KW3E207O2)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	IS1
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80513-301-50	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