

**DAYTIME COLD AND FLU RELIEF SOFTGELS NON-DROWSY- acetaminophen, dextromethorphan hbr, phenylephrine 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.

**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

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

take 2 softgels with water every 4 hours
ask a doctor

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

PUREGEN LABS

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

NON-DROWSY
DAYTIME
COLD & FLU RELIEF

Acetaminophen
Phenylephrine HCl
Dextromethorphan HBr

50
SOFTGELS

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

3 80513 00059 0

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 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
- do not exceed 4 doses per 24 hours

| | |
|---------------------------------------|--|
| 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 |

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

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:80513-301 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------------|----------|
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg |
| DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M) | DIPHENHYDRAMINE HYDROCHLORIDE | 5 mg |
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 325 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |

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

Product Characteristics

| | | | |
|-----------------|------|---------------------|----------|
| Color | red | Score | no score |
| Shape | OVAL | Size | 20mm |
| Flavor | | Imprint Code | IS1 |
| Contains | | | |

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 final | part341 | 04/24/2023 | |

Labeler - Advanced Rx LLC (042795108)

Revised: 5/2023

Advanced Rx LLC