

**DAY TIME COLD AND FLU RELIEF- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled
Shopko Stores Operating Co., 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.

Drug Facts

Active ingredient (in each softgel)

Acetaminophen 325 mg

Dextromethorphan Hydrobromide 10 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

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

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

Sore throat warning: If sore throat is severe, lasts for more than 2 days, occurs with or is followed by fever, headache, rash, nausea, or vomiting, see a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). 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.

Ask a doctor before use if you have

- liver disease
- heart disease
- thyroid disease
- diabetes
- high blood pressure
- 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
- symptoms get worse or last more than 5 days (children) or 7 days (adults)
- 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.

Overdose warning: Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center 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– see Overdose warning
- do not exceed 4 doses per 24 hours

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

- **when using other Day Time or Night Time products, carefully read each label to insure correct dosing**

Other information

- store at room temperature 15°-30°C (59°-86°F) and avoid excessive heat

Inactive ingredients

butylated hydroxyanisole, butylated hydroxytoluene, edible white printing ink, FD&C Red #40*, FD&C

Yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, and sorbitol

*may contain this ingredient

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

**Compare to Vicks® DayQuil® active ingredients

Non Drowsy

Day Time

Cold/Flu Relief Multi-Symptom

Acetaminophen, Dextromethorphan Hydrobromide, Phenylephrine HCl

Pain Reliever/Fever Reducer

Cough Suppressant

Nasal Decongestant

**This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® DayQuil®.

THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE.
USE ONLY IF BLISTERS ARE INTACT.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Package Label Principle Display Panel

NO VARNISH
 NO VARNISH
 1/16 X 1/16 GLUE ASSIST PERF
 FOR MET POLY CTN

1/16 X 1/16 GLUE ASSIST PERF
 FOR MET POLY CTN
 NO VARNISH
 NO VARNISH

Drug Facts (continued)

When using this product do not use more than directed.

Stop use and ask a doctor if ■ you get nervous, dizzy, or sleepless ■ symptoms get worse or last more than 5 days ■ symptoms do not improve after 3 days ■ new symptoms occur ■ cough comes back, or occurs with rash or headache that 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.** Overdose warning: Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center 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 - see Overdose warning ■ do not exceed 4 doses per 24 hours ■ adults and children swallow 2 softgels with water every 4 hours ■ children 4 to under 12 years ask a doctor ■ children under 4 years **do not use**

■ when using other Day Time or Night Time products, carefully read each label to insure correct dosing.

Other information ■ store at room temperature 15°-30°C (59°-86°F) and avoid excessive heat.

Inactive ingredients butylated hydroxytoluene, butylated hydroxyanisole, #40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, povidone, polyethylene glycol, purified water, sorbitan, and sorbitol. *may contain this ingredient.

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

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

Ask a doctor or pharmacist before use if you are ■ 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.

Do not use ■ with any other drug containing acetaminophen (prescription or nonprescription). 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.

Sore throat warning: If sore throat is severe, lasts for more than 2 days, occurs with or is followed by fever, headache, rash, nausea, or vomiting, see a doctor promptly.

Liver warnings: 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.

Warnings: ■ sore throat ■ headache ■ minor aches & pains ■ fever ■ congestion ■ cough due to minor throat & bronchial irritation ■ nasal

Uses temporarily relieves common cold/flu symptoms: ■ nasal congestion ■ cough due to minor throat & bronchial irritation ■ sore throat ■ headache ■ minor aches & pains ■ fever

Active ingredients (in each softgel) **Purpose**

Acetaminophen 325 mg Pain reliever/fever reducer
 Dextromethorphan Hydrobromide 10 mg Cough suppressant
 Phenylephrine HCl 5 mg Nasal decongestant

SHOPKO Non-Drowsy
Day Time
 Cold/Flu Relief Multi-Symptom

Acetaminophen, Dextromethorphan Hydrobromide, Phenylephrine HCl

SHOPKO

**Compare to Vicks® DayQuil® active ingredients

Non-Drowsy
Day Time
 Cold/Flu Relief Multi-Symptom

Acetaminophen, Dextromethorphan Hydrobromide,
 Phenylephrine HCl

Pain Reliever/Fever Reducer
 Cough Suppressant
 Nasal Decongestant



24 Softgels

Packaged by:
 PL Developments
 200 Hicks Street
 Westbury, NY 11590, USA
 ©2012 ShopKo Stores Operating Co., LLC
 www.shopko.com

SHOPKO
 Satisfaction
 Guaranteed

By Refund Or Exchange



PLD-A
 FC000803

THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE.
 USE ONLY IF BLISTERS ARE INTACT.

KEEP OUTER CARTON FOR COMPLETE
 WARNINGS AND PRODUCT INFORMATION

Lot No.:
 Exp. Date:

DAY TIME COLD AND FLU RELIEF

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:370 12-470 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------------------|----------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 325 mg |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U) | |
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| GELATIN (UNII: 2G86QN327L) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A) | |
| POVIDONES (UNII: FZ989GH94E) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0K00R) | |
| SORBITAN (UNII: 6O92ICV9RU) | |
| SORBITOL (UNII: 506T60A25R) | |

Product Characteristics

| | | | |
|----------|---------|--------------|-------------|
| Color | ORANGE | Score | no score |
| Shape | CAPSULE | Size | 20mm |
| Flavor | | Imprint Code | P19;95A;36A |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-------------------|----------------------|----------------------|--------------------|
| 1 | NDC:370 12-470-24 | 2 in 1 CARTON | | |
| 1 | | 12 in 1 BLISTER PACK | | |
| 2 | NDC:370 12-470-20 | 2 in 1 CARTON | | |
| 2 | | 10 in 1 BLISTER PACK | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part341 | 03/25/2011 | |

Labeler - Shopko Stores Operating Co., LLC. (023252638)

Revised: 8/2012

Shopko Stores Operating Co., LLC.