# MULTI-SYMPTOM DAYTIME- acetaminophen, dextromethorphan hydrobromide, and phenylephrine hydrochloride capsule, liquid filled SPIRIT PHARMACEUTICALS LLC

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# **VALUMEDS DAY TIME COLD & FLU MULTI-SYMPTOM RELIEF**

# **Drug Facts**

| 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          |

# Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- cough due to minor throat & 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

# Allergy alert:

acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

# 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 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.

# **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 of age | swallow 2 softgels with water |
|-------------------------------------|-------------------------------|
| and over                            | every 4 hours                 |

| children 4 to under 12 years of age | ask a doctor |
|-------------------------------------|--------------|
| children under 4 years of age       | do not use   |

# If taking Daytime and Nighttime softgels carefully read each label to insure correct dosing

### Other information

- store at room temperature 15°-30°C (59°-86°F) and avoid excessive heat
- this product does not contain phenylpropanolamine

# Inactive ingredients

FD&C Red No. 40, FD&C Yellow No.6. gelatin, glycerin, polyethylene glycol 400, povidone, propylene glycol, purified water, sorbitol sorbitan, titanium dioxide

# Questions or comments?

1-888-333-9792

DISTRIBUTED BY GREENBRIER INTERNATIONAL, INC. 500 VOLVO PARKWAY, CHESAPEAKE, VA 23320

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

PRINCIPAL DISPLAY PANEL - 48 Softgels Blister Pack Carton

SEE NEW WARNINGS INFORMATION

COMPARE TO ACTIVE INGREDIENTS IN VICKS ® DAYQUIL ®\*

**VALUMEDS** ™

**NON-DROWSY** 

**DAY TIME** 

## **COLD & FLU MULTI-SYMPTOM RELIEF**

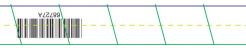
ACETAMINOPHEN, DEXTROMETHORPHAN HBr, PHENYLEPHRINE HCI

Pain Reliever

- Fever Reducer
- Cough Suppressant
- Nasal Decongestant

### 48 SOFTGELS

Liquid filled capsules



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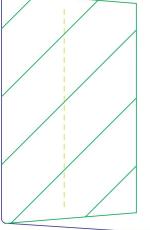
Orug Facts (continued)

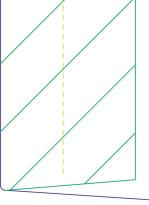
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Drug Facts





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MULTI-SYMPTOM RELIEF

48 SOFTGELS
Liquid filled capsules

# (VALUMEDS )

**COLD & FLU** MULTI-SYMPTOM RELIEF

**VALUMEDS** 

Compare to the active ingredients in VICKS® DAYQUIL®\*

**SEE NEW WARNINGS INFORMATION** 

# **NON-DROWSY**

# **COLD & FLU** MULTI-SYMPTOM RELIEF

ACETAMINOPHEN, DEXTROMETHORPHAN HBr, PHENYLEPHRINE HCI



Nasal Decongestant

**48 SOFTGELS** Liquid filled capsules

 Pain Reliever • Fever Reducer Cough Suppressant

### 71/60 DIRO копкопкота, ит 11779

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

Distributed By: Spirit Pharmaceuticals, LLC

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

Questions or comments? 1-888-333-9792

**ractive ingredients** FD&C Red No. 40, FD&C Yellow No.6. gelatin, glycerin, polyethylene glycol 400, povidone, propylene glycol, purified water bribiol sorbitan, titanium dioxide Orng Facts (continued)

Valumed Daytime Softgel 48ct\_UG.indd 1

EXP.

acetaminophen, dextromethorphan hydrobromide, and phenylephrine hydrochloride capsule, liquid filled

| Product Information     |                |                    |                |
|-------------------------|----------------|--------------------|----------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:68210-1040 |
| Route of Administration | ORAL           |                    |                |

| Active Ingredient/Active Moiety  |                                  |          |  |
|--|----------------------------------|----------|--|
| Ingredient Name  | Basis of Strength                | Strength |  |
| ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)                           | ACETAMINOPHEN                    | 325 mg   |  |
| <b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN<br>HYDROBROMIDE | 10 mg    |  |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)            | PHENYLEPHRINE<br>HYDROCHLORIDE   | 5 mg     |  |

| Inactive Ingredients                       |          |  |  |
|--|----------|--|--|
| Ingredient Name                            | Strength |  |  |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8)       |          |  |  |
| FD&C RED NO. 40 (UNII: WZB9127XOA)         |          |  |  |
| GELATIN (UNII: 2G86QN327L)                 |          |  |  |
| GLYCERIN (UNII: PDC6A3C0OX)                |          |  |  |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) |          |  |  |
| POVIDONE K30 (UNII: U725QWY32X)            |          |  |  |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)        |          |  |  |
| WATER (UNII: 059QF0KO0R)                   |          |  |  |
| SORBITOL (UNII: 506T60A25R)                |          |  |  |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)        |          |  |  |

| Product Characteristics |                    |              |          |
|-------------------------|--------------------|--------------|----------|
| Color                   | orange             | Score        | no score |
| Shape                   | CAPSULE (SOFTGELS) | Size         | 21mm     |
| Flavor                  |                    | Imprint Code | 512      |
| Contains                |                    |              |          |

| Packaging            |   |                         |                       |  |
|----------------------|---|-------------------------|-----------------------|--|
| # Item Code          | Package Description                                     | Marketing Start<br>Date | Marketing End<br>Date |  |
| NDC:68210-<br>1040-0 | 48 in 1 CARTON  | 04/18/2018              |                       |  |
| 1                    | 12 in 1 BLISTER PACK; Type 0: Not a Combination Product |                         |                       |  |

# **Marketing Information**

| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
|-----------------------|---|-------------------------|-----------------------|
| OTC Monograph Drug    | M012  | 04/18/2018              |                       |
|                       |   |                         |                       |

# Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)

Revised: 12/2023 SPIRIT PHARMACEUTICALS LLC