

**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***

<b><i>Active ingredients (in each softgel)</i></b>	<b><i>Purpose</i></b>
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.

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adults and children 12 years of age and over	swallow 2 softgels with water every 4 hours
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children 4 to under 12 years of age	ask a doctor
children under 4 years of age	<b>do not use</b>

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

### **Inactive ingredients**

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

### **Questions or comments?**

**1-888-333-9792**

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

Distributed By:

**Spirit Pharmaceuticals, LLC**

Ronkonkoma, NY 11779

### **PRINCIPAL DISPLAY PANEL**

**COMPARE TO ACTIVE INGREDIENTS IN**

**VICKS<sup>®</sup> DAYQUIL<sup>®\*</sup>**

**VALUMEDS<sup>™</sup>**

**NON-DROWSY**

**DAY TIME**

**COLD & FLU MULTI-SYMPTOM RELIEF**

ACETAMINOPHEN, DEXTROMETHORPHAN HBr, PHENYLEPHRINE HCl

Pain Reliever

- Fever Reducer
- Cough Suppressant
- Nasal Decongestant

**48 SOFTGELS**

Liquid filled capsules



## MULTI-SYMPTOM DAYTIME

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

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68210-5003
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
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### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B6978945GQ)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (SOFTGELS)	<b>Size</b>	21mm
<b>Flavor</b>		<b>Imprint Code</b>	512;A09;AP01
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-5003-4	4 in 1 CARTON	02/17/2023	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	02/17/2023	

**Labeler** - SPIRIT PHARMACEUTICALS LLC (179621011)

Revised: 12/2023

SPIRIT PHARMACEUTICALS LLC