

**MULTI-SYMP TOM NITETIME- acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate capsule, liquid filled SPIRIT PHARMACEUTICALS LLC**

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**VALUMEDS MULTI-SYMP TOM NITE TIME COLD&FLU CAPSULES**

***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 15 mg	Cough suppressant
Doxylamine Succinate 6.25 mg	Antihistamine

***Uses***

temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches/pains
- fever
- runny nose and sneezing

***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, or 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.
- to make a child sleep

### **Ask a doctor before use if you have**

- liver disease
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
- trouble urinating due to enlarged prostate gland

### **Ask a doctor or pharmacist before use if you are**

- taking sedatives or tranquilizers
- taking the blood-thinning drug warfarin.

### **When using this product**

- **do not use more than directed**
- excitability may occur especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives and tranquilizers may increase drowsiness

### **Stop use and ask a doctor if**

- pain or cough gets worse or lasts 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**

**Overdose warning:** Taking more than the recommended dose 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 as well as for children, even if you do not notice any signs or symptoms.

### **Directions**

- Take only as recommended—see **Overdose warning.**
- do not exceed 4 doses per 24 hours

adults and children 12 years of age and over	swallow 2 softgels with water every 6 hours
children 4 to under 12 years of age	ask a doctor
children under 4 years of age	<b>do not use</b>

**If taking Nighttime and Daytime 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***

D&C Yellow No. 10, FD&C Blue No. 1, gelatin, glycerin, polyethylene glycol 400, povidone, propylene glycol, purified water, sorbitol sorbitan, titanium dioxide

***Questions or comments?***

**1-888-333-9792**

Distributed By:

Spirit Pharmaceuticals, LLC

Ronkonkoma, NY 11779

**PRINCIPAL DISPLAY PANEL - 48 COUNT BLISTER CARTON**

**VALUMEDS™**

SEE NEW WARNINGS INFORMATION

**Compare to the active ingredients**

in **VICKS® NyQUIL®\***

**MULTI-SYMP TOM**

**NITE TIME**

**COLD&FLU NIGHTTIME RELIEF**

ACETAMINOPHEN, DEXTROMETHORPHAN HBr, DOXYLAMINE SUCCINATE

- Pain Reliever
- Fever Reducer
- Cough Suppressant
- Antihistamine

## **48 SOFTGELS**

Liquid filled capsules



**Drug Facts (continued)**

**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 the product.
- with other drugs containing acetaminophen.
- 3 or more alcoholic drinks every day while using this product.

**Minority alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:
 

- skin redness
- blister
- rash
- swelling of the face, lips, or throat
- itching
- fever

**Severe throat warning:** If your throat is severe, lasts for more than 2 days, or 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 nonnarcotic cough suppressant (MADL) (certain drugs for depression, psychotic or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MADL drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- to make a child sleep.

**Ask a doctor before use if you have:** liver disease, glaucoma, or cough that occurs with too much phlegm (mucus).
 **Directions**

- Take over as recommended—see **Overdose warning**.
- do not exceed 4 doses per 24 hours.
- swallow 2 softgels with water every 6 hours.
- ask a doctor if you are under 17 years of age.
- children under 4 years of age do not use.

**Keep out of reach of children.** If pregnant or breast-feeding, ask a health professional before use. These could be signs of a serious condition:
 

- cough comes back or occurs with rash, or headache that lasts.
- fever gets worse or lasts more than 3 days.
- new symptoms occur.
- redness or swelling is present.
- skin rash or hives more than 7 days.
- pain or cough gets worse or lasts more than 7 days.

**Stop use and ask a doctor if:**

- alcohol, sedatives and tranquilizers may increase drowsiness.
- be careful when driving a motor vehicle or operating machinery.
- marked drowsiness may occur.
- avoid alcoholic drinks.
- excitability may occur especially in children.
- headache.
- minor aches/pains.
- fever.

**When using this product:**

- do not use more than directed.
- avoid alcohol.
- avoid driving a motor vehicle or operating machinery.
- avoid alcoholic drinks.
- marked drowsiness may occur.
- avoid alcoholic drinks.
- excitability may occur especially in children.
- headache.
- minor aches/pains.
- fever.

**When using this product:**

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- avoid driving a motor vehicle or operating machinery.
- avoid alcoholic drinks.
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- avoid alcoholic drinks.
- excitability may occur especially in children.
- headache.
- minor aches/pains.
- fever.

**When using this product:**

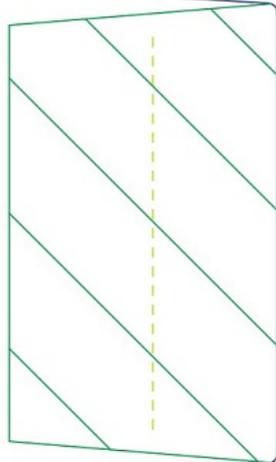
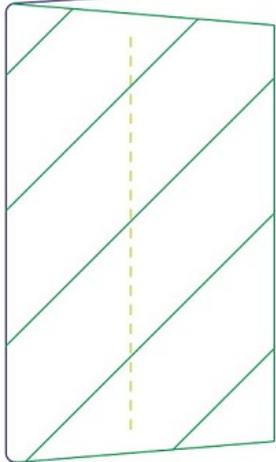
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**VALUMEDS**  
**MULTI-SYMP TOM**  
**NITE TIME**  
**COLD & FLU NIGHTTIME RELIEF**

**VALUMEDS** SEE NEW WARNINGS INFORMATION  
 Compare to the active ingredients in **VICKS® NyQUIL®**  
**MULTI-SYMP TOM**  
**NITE TIME**  
**COLD & FLU NIGHTTIME RELIEF**  
 ACETAMINOPHEN, DEXTROMETHORPHAN HBr, DOXYLAMINE SUCCINATE

- Pain Reliever
- Fever Reducer
- Cough Suppressant
- Antihistamine



**48 SOFTGELS**  
 Liquid filled capsules

**VALUMEDS**  
**MULTI-SYMP TOM**  
**NITE TIME**  
**COLD & FLU NIGHTTIME RELIEF**  
**48 SOFTGELS**  
 Liquid filled capsules

**Drug Facts (continued)**

**Other information**

- Store at room temperature 15°-30°C (59°-86°F) and avoid excessive heat.
- This product does not contain phenylephrine.
- Contains 48 softgels.
- Contains 100 mg of acetaminophen per softgel.
- Contains 10 mg of dextromethorphan HBr per softgel.
- Contains 2 mg of doxylamine succinate per softgel.
- Contains 10 mg of chlorpheniramine maleate per softgel.

**Inactive ingredients:** D&C Yellow No. 10, FD&C Blue No. 1, gelatin, glycerin, polyethylene glycol 400, polyethylene glycol 600, polyethylene glycol 800, polyethylene glycol 1000, polyethylene glycol 1500, polyethylene glycol 2000, polyethylene glycol 3000, polyethylene glycol 4000, polyethylene glycol 6000, polyethylene glycol 8000, polyethylene glycol 10000, polyethylene glycol 15000, polyethylene glycol 20000, polyethylene glycol 30000, polyethylene glycol 40000, polyethylene glycol 60000, polyethylene glycol 80000, polyethylene glycol 100000, polyethylene glycol 150000, polyethylene glycol 200000, polyethylene glycol 300000, polyethylene glycol 400000, polyethylene glycol 600000, polyethylene glycol 800000, polyethylene glycol 1000000.

**Questions or comments?** 1-888-333-9192

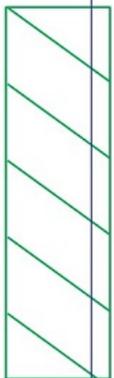
**Distributed By:**  
 Spirit Pharmaceuticals, LLC  
 Ronkonkoma, NY 11779  
 ORIG 06/17

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

ITEM#60516-1

0 140232 60516 1

LOT: EXP:



acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate capsule, liquid filled

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68210-1050
<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	15 mg
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<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)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GELATIN</b> (UNII: 2G86QN327L)	

## Product Characteristics

<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (SOFTGELS)	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	215
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-1050-0	48 in 1 CARTON	04/16/2018	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:68210-1050-1	1 in 1 CARTON	04/16/2018	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:68210-1050-2	2 in 1 CARTON	09/15/2020	

3	12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M012	04/16/2018	

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

Revised: 12/2024

SPIRIT PHARMACEUTICALS LLC