

**MULTI-SYMPTOM NIGHTTIME- acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate capsule, liquid filled**  
**SPIRIT PHARMACEUTICALS LLC**

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**MULTI-SYMPTOM NIGHTTIME COLD & FLU**

***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, lecithin, myglyol, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan, titanium dioxide

**Questions or comments?**

**1-888-333-9792**

**PRINCIPAL DISPLAY PANEL**

Nighttime

Multi-symptom

Cold & Flu

Acetaminophen - Pain Reliever / Fever Reducer

Dextromethorphan HBr - Cough Suppressant

Doxylamine Succinate - Antihistamine

Relief of:

- Headache & Fever • Sore Throat • Minor Aches & Pains
- Cough • Sneezing & Runny Nose

10 Softgels



VALORHEALTH BY SPIRIT

LiquiCaps™ active ingredients†

# nighttime cold & flu

Multi-symptom

**Acetaminophen - Pain Reliever / Fever Reducer**  
**Dextromethorphan HBr - Cough Suppressant**  
**Doxylamine Succinate - Antihistamine**

Relief of:

- Headache & Fever • Sore Throat • Minor Aches & Pains
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Actual Size

**10 softgels**

89919-2  
 50026 889 19 2  
 8

Manufactured by Spirit Pharmaceuticals, LLC  
 1779 Old York Rd  
 York, PA 17402

This product is not manufactured or distributed by Proctor & Gamble, owner of the registrer trademarks Vicks® NyQuil™ LiquiCaps™

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION**  
**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING**

<p><b>Drug Facts (continued)</b></p> <p><b>Other information</b></p> <p>store between 15°C to 30°C (59°F to 86°F)</p> <p>propylene glycol, purified water, sorbitol sorbita, titanium dioxide, gelatin, glycerin, lecithin, mygrol, polyethylene glycol, povidone</p> <p><b>Drug Facts (continued)</b></p> <p><b>Questions or comments?</b> 1-888-333-9792</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>with any other drug containing acetaminophen (prescription or nonprescription), if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</li> <li>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.</li> <li>Ask a doctor before use if you have liver disease or glucose MAOI, ask a doctor or pharmacist before taking this product.</li> </ul> <p><b>Warnings</b></p> <p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 8 softgels in 24 hours, which is the maximum daily amount for this product. <p>with other drugs containing acetaminophen</p> <p>3 or more alcoholic drinks daily while using this product</p> <p><b>Allergy alert:</b> Acetaminophen may cause severe skin reactions. Symptoms may include: skin redness, hives, blisters, rash</p> <p>If a skin reaction occurs, stop use and seek medical help right away.</p> <p><b>Sore throat warning:</b> If sore throat is severe, lasts for more than 2 days, or occurs with or is followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.  <p><b>Uses</b></p> <p>temporarily relieves common cold/flu symptoms: cough due to minor throat and bronchial irritation</p> <p>Acetaminophen 325 mg      Dextromethorphan HBr 15 mg      Doxylamine Succinate 6.25 mg</p> <p><b>Purpose</b></p> <p>Pain reliever/fever reducer      Cough suppressant      Antihistamine</p> </p></p>						
<p><b>Drug Facts (continued)</b></p> <p><b>When using this product, do not use more than directed</b></p> <ul style="list-style-type: none"> <li>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers</li> <li>being sedatives or tranquilizers</li> <li>bing the blood thinning drug warfarin.</li> </ul> <p><b>When using this product, do not use more than directed</b></p> <ul style="list-style-type: none"> <li>excitability may occur, especially in children</li> <li>raked or drowsiness may occur</li> <li>avoid alcoholic drinks</li> <li>be careful when driving a motor vehicle or operating machinery</li> <li>alcohol, sedatives and tranquilizers may increase drowsiness</li> </ul> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>pain or cough gets worse or lasts more than 7 days</li> <li>fever gets worse or lasts more than 3 days</li> <li>redness or swelling is present</li> <li>cough comes back or occurs with rash or headache that lasts</li> </ul> <p><b>If pregnant or breast-feeding, ask a health professional before use.</b></p> <p><b>Keep out of reach of children.</b></p> <p>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.  <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>take only as directed</li> <li>do not exceed 8 softgels per 24 hours</li> </ul> <p>adults and children 12 years and over</p> <table border="1"> <tr> <td>ask a doctor and over</td> <td>2 softgels with water every 6 hours</td> </tr> <tr> <td>childen 4 to under 12 years</td> <td>ask a doctor</td> </tr> <tr> <td>childen under 4 years</td> <td>do not use</td> </tr> </table> <p><b>When using other Daytime or Nightime products, carefully read each label to ensure correct dosing</b></p> </p>	ask a doctor and over	2 softgels with water every 6 hours	childen 4 to under 12 years	ask a doctor	childen under 4 years	do not use	<p><b>Drug Facts (continued)</b></p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>with any other drug containing acetaminophen (prescription or nonprescription), if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</li> <li>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.</li> <li>Ask a doctor before use if you have liver disease or glucose MAOI, ask a doctor or pharmacist before taking this product.</li> </ul> <p><b>Warnings</b></p> <p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 8 softgels in 24 hours, which is the maximum daily amount for this product. <p>with other drugs containing acetaminophen</p> <p>3 or more alcoholic drinks daily while using this product</p> <p><b>Allergy alert:</b> Acetaminophen may cause severe skin reactions. Symptoms may include: skin redness, hives, blisters, rash</p> <p>If a skin reaction occurs, stop use and seek medical help right away.</p> <p><b>Sore throat warning:</b> If sore throat is severe, lasts for more than 2 days, or occurs with or is followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.  <p><b>Uses</b></p> <p>temporarily relieves common cold/flu symptoms: cough due to minor throat and bronchial irritation</p> <p>Acetaminophen 325 mg      Dextromethorphan HBr 15 mg      Doxylamine Succinate 6.25 mg</p> <p><b>Purpose</b></p> <p>Pain reliever/fever reducer      Cough suppressant      Antihistamine</p> </p></p>
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**MULTI-SYMPTOM NITETIME**  
 acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate capsule, liquid filled

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68210-5002
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<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: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35S5USQ3G)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<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: 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)	

## Product Characteristics

<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (OBLONG)	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	215;902;AP02
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-5002-1	1 in 1 CARTON	12/07/2022	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC Monograph Drug	M012	12/07/2022	

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

Revised: 12/2024

SPIRIT PHARMACEUTICALS LLC