

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

MULTI-SYMPATOM NIGHTTIME COLD & FLU

Drug Facts

<i>Active ingredients (in each softgel)</i>	<i>Purpose</i>
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	do not use

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
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Relief of:

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Actual Size

10 softgels

Manufactured by Spirit Pharmaceuticals, LLC
 Anderson, NY 11779 086 0761
 Made in India



88919-2

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>Drug Facts (continued)</p> <p>Other information ■ store between 15°C to 30°C (59°F to 86°F)</p> <p>Inactive ingredients D&C Yellow No. 10, FD&C Blue No. 1</p>	<p>Drug Facts (continued)</p> <p>propylene glycol, purified water, sorbitol sorbita, titanium dioxide, gelatin, glycerin, lecithin, myrtil, polyethylene glycol, povidone</p> <p>Questions or comments? 1-888-333-9792</p>
<p>Drug Facts (continued)</p> <p>Do not use ■ with any other drug containing acetaminophen (prescription or non-prescription), 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 ■ glucose ■ cough that occurs with too much phlegm (mucus)</p> <p>Warnings ■ 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. ■ With other drugs containing acetaminophen ■ Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin redness ■ 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, consult a doctor promptly.</p> <p>Uses Temporarily relieves common cold/flu symptoms: ■ cough due to minor throat and bronchial irritation ■ sore throat ■ headache ■ minor aches and pains ■ fever ■ runny nose and sneezing</p> <p>Active ingredients (in each softgel) Acetaminophen 325 mg Pain reliever/fever reducer Dextromethorphan HBr 15 mg Cough suppressant Doxylamine Succinate 6.25 mg Antihistamine</p>	<p>Drug Facts (continued)</p> <p>When using this product, do not use more than directed ■ taking sedatives or tranquilizers ■ taking the blood thinning drug warfarin. ■ Ask a doctor or pharmacist before use if you are ■ taking sedatives or tranquilizers ■ taking the blood thinning drug warfarin. ■ taking sedatives or tranquilizers ■ taking the blood thinning drug warfarin.</p> <p>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.</p> <p>If pregnant or breast-feeding, ask a health professional before use. ■ Keep out of reach of children. ■ 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> <p>Directions ■ Take only as directed ■ Do not exceed 8 softgels per 24 hours adults and children 12 years and over 2 softgels with water every 6 hours ask a doctor ■ do not use children under 4 years childen under 12 years</p> <p>When using other Daytime or Nightime products, carefully read each label to ensure correct dosing</p>



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MULTI-SYMPTOM NITETIME

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-5002
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	15 mg
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
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	green	Score	no score
Shape	CAPSULE (OBLONG)	Size	20mm
Flavor		Imprint Code	215;902;AP02
Contains			

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: 12/2023

SPIRIT PHARMACEUTICALS LLC