

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

VALUMEDS MULTI-SYMP TOM NITE TIME COLD&FLU CAPSULES

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, 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)

Purpose
 Acetaminophen 325 mg Pain reliever/fever reducer
 Dextromethorphan Hydrobromide 15 mg Cough suppressant
 Doxylamine Succinate 2 mg Antihistamine

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
 ■ or more alcoholic drinks every day while using this product.
Minority alert: Acetaminophen may cause severe skin reactions.
 Symptoms may include:
 ■ skin redness ■ blisters ■ rash
 ■ severe itching ■ sores ■ peeling ■ blisters ■ rash
 If a skin reaction occurs, stop use and seek medical help right away.
Severe 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 nonsteroidal anti-inflammatory drug (NSAID) (certain drugs for depression, psychotic or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the NSAID drug. If you do not know if your prescription drug contains an NSAID, 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)

Directions ■ Take over as recommended—see **Overdose warning**.
 ■ do not exceed 4 doses per 24 hours
 ■ swallow 2 softgels with water every 6 hours
 ■ adults and children 17 years of age and over
 ■ children 4 to under 17 years of age
 ■ do not use
 ■ children under 4 years of age

Keep out of reach of children.
 In case of overdose, get medical help or cause serious health problems. In case of overdose, get medical help or cause serious health problems, even if you do not notice any signs or symptoms.

Overdose warning: Taking more than the recommended dose can cause serious health problems. In case of overdose, get medical help or cause serious health problems, even if you do not notice any signs or symptoms.

Keep out of reach of children.
 In case of overdose, get medical help or cause serious health problems, even if you do not notice any signs or symptoms.

Stop use and ask a doctor if:
 ■ cough comes back or occurs with rash, or headache that lasts.
 ■ these could be signs of a serious condition.
 ■ coughing, sore throat, or hoarseness occurs.
 ■ 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.

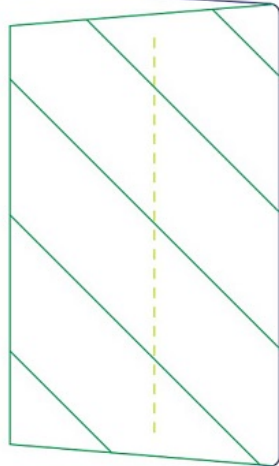
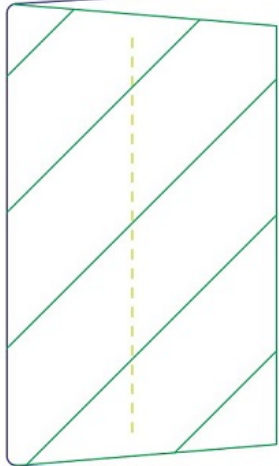
When using this product, do not use more than directed.
 ■ avoid alcoholic drinks
 ■ avoid driving a motor vehicle or operating machinery
 ■ avoid alcohol, sedatives and tranquilizers may increase drowsiness
 ■ alcohol, sedatives and tranquilizers may increase drowsiness

Other Information
 ■ Store at room temperature 15°-30°C (59°-86°F) and avoid excessive heat.
 ■ This product does not contain phenylephrine.
 ■ Inactive ingredients: D-AC Yellow No. 10, FD&C Blue No. 1, gelatin, glycerin, polyethylene glycol 400, polydioxane, propylene glycol, purified water, sorbitol sorbitan, titanium dioxide.

Questions or comments? 1-888-333-9172

Other Information
 ■ This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® NyQuil®.

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



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



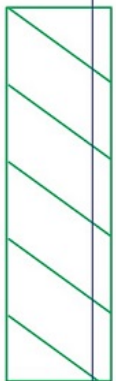
48 SOFTGELS
 Liquid filled capsules

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

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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-1050
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: V9BI9B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
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)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	

Product Characteristics

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

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		
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	04/16/2018	

Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)

Revised: 12/2023

SPIRIT PHARMACEUTICALS LLC