MULTI-SYMPTOM DAYTIME- acetaminophen, dextromethorphan hydrobromide, and phenylephrine hydrochloride capsule, liquid filled
SPIRIT PHARMACEUTICALS LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

VALUMEDS DAY TIME COLD & FLU MULTI-SYMPTOM RELIEF

Drug Facts

Active ingredients (in each softgel)	***Purpose***
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.

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

If taking Daytime and Nighttime 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

FD&C Red No. 40, FD&C Yellow No.6. gelatin, glycerin, polyethylene glycol 400, 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.

PRINCIPAL DISPLAY PANEL

SEE NEW WARNINGS INFORMATION

COMPARE TO ACTIVE INGREDIENTS IN
VICKS ® DAYQUIL ®*

VALUMEDS™

NON-DROWSY

DAY TIME

COLD & FLU MULTI-SYMPTOM RELIEF

ACETAMINOPHEN, DEXTROMETHORPHAN HBr, PHENYLEPHRINE HCl

Pain Reliever
- Fever Reducer
- Cough Suppressant
- Nasal Decongestant

16 SOFTGELS

Liquid filled capsules

MULTI-SYMPTOM DAYTIME

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

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68210-4010
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	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
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)	

Product Characteristics

Color	orange	**Score**	no score
Shape	CAPSULE (SOFTGELS)	**Size**	21mm
Flavor		**Imprint Code**	512
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-4010-1	2 in 1 CARTON	09/23/2019	
1		16 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 final	part341	04/18/2018	

Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)

Establishment

Name	Address	ID/FEI	Business Operations
MEDGEL PRIVATE LTD		677385498	manufacture(68210-4010)

Revised: 3/2020 SPIRIT PHARMACEUTICALS LLC