CVS DAYTIME SEVERE COLD AND FLU RELIEF SOFTGELS- acetaminohpen, dextromethorphan hbr, guaifenesin, phenylephrine hcl capsule, liquid filled
CVS Pharmacy

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.

CVS Daytime Severe Cold and Flu Relief

Active ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethoprhan HBr 10 mg

Guaifenesin 200 mg

Phenlyephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Uses

- ■ temporarily relieves common cold/flu symptoms: ■ nasal congestion ■ sinus congestion & pressure ■ cough due to minor throat & bronchial irritation ■ minor aches & pains ■ headache ■ fever ■ sore throat ■ reduces swelling of nasal passages ■ temporarily restores freer breathing through the nose ■ promotes nasal and/or sinus drainage ■ helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.

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
- 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, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult 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
- diabetes
- heart disease
- thyroid disease
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough that occurs with too much phlegm (mucus)

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 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: Taking more than the recommended dose can cause liver damage. 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 directed
■ do not exceed 8 softgels per 24 hours

adults & children 12 years & over	2 softgels with water every 4 hours
children 4 to under 12 years	ask a doctor
children under 4 years	do not use

■ when using other Nighttime or Daytime products, carefully read each label to ensure correct dosing

Other information

- ■ store at room temperature

Inactive ingredients

FD&C Yellow # 6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide

Questions or comments? 1-888-333-9792

Principal Display Panel

Compare to the active ingredients in Vick® DayQuil® Cold & Flu*

MAXIMUM STRENGTH

Daytime Softgels

Severe Cold/Flu Relief

ACETAMINOPHEN - Pain reliever; fever reducer

DEXTROMETHORPHAN HBr - Cough Suppressant

GUAIFENESIN- Expectorant

PHENYLEPHRINE HCl - Nasal Decongestant

Relieves:
Headache, Fever, Sore throat, Minor aches & pains, Cough, Chest congestion, Nasal/Sinus congestion & Sinus pressure
Non-drowsy
Alcohol free
Antihistamine free

24 SOFTGELS

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

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Vicks® DayQuil® Severe Cold
& Flu.

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V-35249

CVS DAYTIME SEVERE COLD AND FLU RELIEF SOFTGELS

acetaminohpen, dextromethorphan hbr, guaifenesin, phenylephrine hcl capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69842-545
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
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange (Light Orange)	**Score**	no score
Shape	CAPSULE (oblong shaped)	**Size**	20mm
Flavor		**Imprint Code**	341
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-545-24	2 in 1 CARTON	06/05/2019	
1		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 final	part341	06/05/2019	

Labeler - CVS Pharmacy (062312574)

Registrant - Spirit Pharmaceuticals LLC (179621011)

Establishment

Name	Address	ID/FEI	Business Operations
MEDGEL PRIVATE LTD		677385498	manufacture(69842-545)