

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

Non-Drowsy DAYTIME COLD & FLU MULTI-SYMPTOM

Drug Facts

Active ingredients (in each softgel)

Purposes

Acetaminophen 325 mg.....Pain reliever/fever reducer
Dextromethorphan hydrobromide 10 mg.....Cough suppressant
Phenylephrine hydrochloride 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 10 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

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

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

- do not take more than the recommended dose
- adults and children 12 years and over: take 2 softgels with water every 4 hours. Do not exceed 10 softgels in 24 hours or as directed by a doctor.
- children under 12 years: do not use

Other information

- store at room temperature. Avoid excessive heat above 40°C (104°F).

Inactive ingredients

FD&C Red No. 40, FD&C Yellow No.6. gelatin, glycerin, lecithin, polyethylene glycol 400, povidone, propylene glycol, purified water, sorbitol sorbitan, titanium dioxide

Questions or comments?

1-888-333-9792

PRINCIPAL DISPLAY PANEL

Multi-symptom

Non-drowsy Daytime
Cold & Flu

Acetaminophen - Pain Reliever / Fever Reducer
Dextromethorphan HBr - Cough Suppressant
Phenylephrine HCl - Nasal Decongestant

Relief of:

- Headache • Body Ache • Sore Throat
- Nasal Congestion • Sinus Pressure • Cough

10 Softgels

<p>Drug Facts</p> <p>Active ingredients (in each softgel)</p> <p>Acetaminophen 325 mg.....Pain reliever/fever reducer Dextromethorphan hydrobromide 10 mg.....Cough suppressant Phenylephrine hydrochloride 5 mg.....Nasal decongestant</p>	<p>Drug Facts (continued)</p> <p>MAOI, ask a doctor or pharmacist before taking this product. <ul style="list-style-type: none"> ■ if you have ever had an allergic reaction to this product or any of its ingredients ■ in children under 12 years of age </p>
<p>Uses</p> <ul style="list-style-type: none"> ■ temporarily relieves these symptoms due to a cold or flu: <ul style="list-style-type: none"> ■ minor aches and pains ■ headache ■ cough ■ sore throat ■ nasal and sinus congestion ■ temporarily reduces fever 	<p>Ask a doctor before use if you have ■ liver disease ■ heart disease <ul style="list-style-type: none"> ■ high blood pressure ■ thyroid disease ■ diabetes ■ cough with excessive phlegm (mucus) ■ difficulty in urination due to enlargement of the prostate gland ■ persistent or chronic cough such as occurs with smoking, asthma, or emphysema </p>
<p>Warnings</p> <p>Liver warning This product contains acetaminophen. Severe liver damage may occur if you take <ul style="list-style-type: none"> ■ more than 4,000 mg of acetaminophen in 24 hours ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product <p>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.</p> <p>Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash <ul style="list-style-type: none"> ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock <p>If a skin or general allergic reaction occurs, stop use and seek medical help right away.</p> </p></p>	<p>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin</p> <p>When using this product do not exceed recommended dosage</p> <p>Stop use and ask a doctor if ■ pain, cough, or nasal congestion gets worse or lasts more than 7 days <ul style="list-style-type: none"> ■ 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. ■ nervousness, dizziness, or sleeplessness occurs </p> <p>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. <p>In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.</p> </p>
<p>Do not use</p> <ul style="list-style-type: none"> ■ 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 	<p>Directions ■ do not take more than the recommended dose <ul style="list-style-type: none"> ■ adults and children 12 years and over: take 2 softgels with water </p>



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 every 4 hours. Do not exceed 10 softgels in 24 hours or as directed by a doctor.
 children under 12 years: do not use

Drug Facts (continued)
Other information
 ■ store at room temperature. Avoid excessive heat above 40°C (104°F).
Inactive ingredients FD&C Red No. 40, FD&C Yellow No. 6, ▶

Drug Facts (continued)
 gelatin, glycerin, lecithin, myglyol, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan, titanium dioxide
Questions or comments? 1-888-333-9792

This product is not manufactured or distributed by Bayer Healthcare LLC, owner of the registered trademark Alka-Seltzer Plus®.
KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION
TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF PLUSTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

88903-1
 8 50026188903 1
 Made in India
 Distributed by: Spirit Pharmaceuticals, LLC
 Ronkonkoma, NY 11779 CHG 01/21
 LOT:
 EXP:

MULTI-SYMPTOM DAYTIME

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

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-5000
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: 9D2RT19KYH) (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)	
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)	
SORBITAN (UNII: 6O92ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red (Orange to Red)	Score	no score
Shape	CAPSULE (OBLONG)	Size	21mm
Flavor		Imprint Code	512;A09;AP01
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-5000-1	1 in 1 CARTON	12/07/2022	
1		10 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	12/07/2022	

Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)