

**DAYTIME COLD AND FLU MAX MAXIMUM STRENGTH SOFTGELS-  
acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid  
filled**

**Topco Associates, LLC**

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**Daytime Cold and Flu Max Softgels**

***Drug Facts***

***Active ingredient (in each softgel)***

Acetaminophen 325 mg  
Dextromethorphan HBr 10 mg  
Phenylephrine HCl 5 mg

***Purpose***

Pain reliever/fever reducer  
Cough suppressant  
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 8 Softgels in 24 hrs, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily 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 is 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
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- 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 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.

**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 (1-800-222-1222) right away. Quick medical attention is critical for adults & for children even if you do not notice any signs or symptoms.

### **Directions**

**take only as directed do not exceed 8 softgels per 24 hrs**

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adults & children 12 yrs & over

2 Softgels with water every 4 hrs

children 4 to under 12 yrs

ask a doctor

children under 4 yrs

do not use

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### **Other information**

- store between 20-25°C (68-77°F).  
Avoid high humidity and excessive heat.  
Protect from light.

***Questions or comments?***

**1-800-373-6981** (toll-free)

***Inactive ingredients***

FD&C Yellow No. 6, gelatin, glycerin, isopropyl alcohol, MCT Oil, polyethylene glycol-400, propylene glycol, povidone, purified water, silver sheen, sorbitol solution

Distributed by:

**Topco Associates LLC**

Itasca, IL 60143

**PRINCIPAL DISPLAY PANEL**

TopCare health

Compare to the Active Ingredients in Alka-Seltzer Plus® Maximum Strength Daytime Cold & Flu Powermax Gels

Non-Drowsy  
Daytime  
Cold & Flu Max  
Softgels

Maximum Strength

Carton



## DAYTIME COLD AND FLU MAX MAXIMUM STRENGTH SOFTGELS

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76162-912
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>BUTYLATED HYDROXYANISOLE</b> (UNII: REK4960K2U)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	

<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C00X)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	SD14
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76162-912-24	2 in 1 CARTON	09/25/2024	
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 Drug	M012	09/25/2024	

**Labeler** - Topco Associates, LLC (006935977)

Revised: 9/2024

Topco Associates, LLC