

**DAYTIME SEVERE COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, film coated**  
**Spirit Pharmaceuticals LLC**

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**Daytime Severe Cold and Flu**

***Drug Facts***

***Active ingredients (in each caplet)***

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5

***Purpose***

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

***Uses***

• for the temporary relief of the following cold/flu symptoms: • minor aches and pains • headache • sore throat • nasal congestion • cough • helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive • temporarily reduces fever

***Warnings***

**Liver warning:** This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. Severe liver damage may occur if you take:

- 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

**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.
- if you have ever had an allergic reaction to this product or any of its ingredients.

### **Ask a doctor before use if you have**

- liver disease • heart disease • high blood pressure • thyroid disease • diabetes • trouble urinating due to an enlarged prostate gland • persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis 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 exceed recommended dosage**

### **Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur • 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.**

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.

**Directions**

do not take more than directed

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adults and children 12 years & over	• take 2 caplets every 4 hours • swallow whole; do not crush, chew or dissolve • do not take more than 10 caplets in 24 hours
children under 12 years	ask a doctor

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**Other information**

store at 25°C (77°F); excursions permitted between 15°–30°C (59°–86°F)

**Inactive Ingredients**

croscarmellose sodium, D&C Yellow#10, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone\*, pregelatinized starch, talc, titanium dioxide \*may contain this ingredient

**Questions or comments?**

**1-888-333-9792**

**Distributed by:**

Cabinet Health P.B.C.

**Pouch**



COMPOSTABLE  
REFILL POUCH



# CABINET:

## Daytime Severe Cold & Flu Refill

COMPARE TO THE ACTIVE INGREDIENTS IN:

**Tylenol® Cold + Flu Severe\***

Acetaminophen 325 mg, Dextromethorphan HBr 10 mg,  
Guaifenesin 200 mg, Phenylephrine HCl 5 mg

RELIEVES:

HEAD & BODY ACHES • FEVER & SORE THROAT • COUGH  
NASAL CONGESTION • MUCUS & CHEST CONGESTION

30 CAPLETS



# TO OPEN:

1. POSITION THUMBS INSIDE THE SHORT FLANGE OVER THE LOCKS.
2. GRIP WHILE PIVOTING THUMBS OUTWARD TO OPEN THE LOCKS.

*Tamper evident: do not use if pouch is open*

## Drug Facts

### Active ingredient (in each caplet)

### Purpose

Acetaminophen 325 mg..... Pain reliever/fever reducer  
Dextromethorphan HBr 10 mg ..... Cough suppressant  
Guaifenesin 200 mg..... Expectorant  
Phenylephrine HCl 5 mg ..... Nasal decongestant

**Uses** • for the temporary relief of the following cold/flu symptoms:  
• minor aches and pains • headache • sore throat • nasal congestion  
• cough • helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive • temporarily reduces fever

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• 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 **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. • If you have ever had an allergic reaction to this product or any of its ingredients.

### Ask a doctor before use if you have

• liver disease • heart disease • high blood pressure • thyroid disease  
• diabetes • trouble urinating due to an enlarged prostate gland • persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis 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 exceed recommended dose

**Stop use and ask a doctor if** • nervousness, dizziness, or sleeplessness occur • 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 warnings:** 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.

## Drug Facts (continued)

### Directions • do not take more than directed

adults and children over 12 years old	• take 2 caplets every 4 hours • swallow whole; do not crush, chew or dissolve • do not take more than 10 caplets in 24 hours
children under 12 years	ask a doctor

**Other information** • store at 25°C (77°F); excursions permitted between 15°–30°C (59°–86°F)

**Inactive ingredients** Croscarmellose sodium, D&C Yellow #10, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone\*, pregelatinized starch, talc, titanium dioxide \*may contain this ingredient

### Questions or comments?

1-888-333-6792

\*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® Cold + Flu Severe

† Less than the limit of detection and consistent with gluten-free diet labeling per FDA

NDC: 68210-4187-2

ACC-1-10033  
Distributed by: Cabinet Health P.B.O.  
Question/Comments? 1-888-333-6792  
www.cabinethealth.com

Lot / Expiration ▼



Compostable  
& Plastic Free



Independently  
Quality Tested



Gluten Free  
Verified†

# DAYTIME SEVERE COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68210-4167
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>STARCH, POTATO</b> (UNII: 8I089SAH3T)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	yellow	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	ET32
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:68210-4167-2	20 in 1 POUCH; Type 0: Not a Combination Product	11/19/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	11/19/2021	

**Labeler** - Spirit Pharmaceuticals LLC (179621011)

Revised: 12/2023

Spirit Pharmaceuticals LLC