

**SEVERE COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, coated**  
**Chain Drug Marketing Association**

*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.*

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**1163 - QCH - 2014-1030**

***Drug Facts***

<b><i>Active ingredients (in each caplet)</i></b>	<b><i>Purpose</i></b>
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

**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

**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.**

**Overdose warning**

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 (see overdose warning)**

adults and children 12 years and over	<ul style="list-style-type: none"><li>▪ take 2 caplets every 4 hours</li><li>▪ swallow whole – do not crush, chew, or dissolve</li><li>▪ do not take more than 10 caplets in 24 hours</li></ul>
children under 12 years	<ul style="list-style-type: none"><li>▪ ask a doctor</li></ul>

**Other information**

- store between 20-25°C (68-77°F) in a dry place
- retain carton for complete product information

**Inactive ingredients**

acesulfame potassium, colloidal silicon dioxide, corn starch, croscarmellose sodium, crospovidone,

D&C yellow #10, FD&C blue #2, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

**PRINCIPAL DISPLAY PANEL**

NDC 63868-003-24

QUALITY CHOICE

†Compare to TYLENOL® Cold & Flue Severe active ingredients

Severe Cold & Flu

For Adults

Pain Reliever / Fever Reducer, Nasal Decongestant, Cough Suppressant, Expectorant

Acetaminophen, Phenylephrine HCl, Dextromethorphan HBr, Guaifenesin

For Relief of:

Headache / Fever / Sore Throat

Nasal Congestion

Cough / Chest Congestion

Clears Out Mucus

24 Cool Taste Caplets

SEE NEW WARNINGS INFORMATION & DIRECTIONS

NDC

NDC

NDC

**Drug Facts (continued)**

**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  
**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied 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  
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**Directions**  
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 ■ take 2 caplets every 4 hours  
 ■ swallow whole – do not crush, chew, or dissolve  
 ■ do not take more than 10 caplets in 24 hours  
 ■ ask a doctor  
 children under 12 years

**Overdose warning:** 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.

**Keep out of reach of children.**  
 If pregnant or breast-feeding, ask a health professional before use. These could be signs of a serious condition.  
 ■ cough comes back or occurs with rash or headache that lasts  
 ■ redness or swelling is present ■ new symptoms occur  
 ■ fever gets worse or lasts more than 3 days  
 ■ pain, nasal congestion, or cough gets worse or lasts more than 7 days  
 ■ nervousness, dizziness, or sleeplessness occur

**Stop use and ask a doctor if**  
 ■ cough that occurs with too much phlegm (mucus) thinning drug warfarin

**When using this product do not exceed recommended dosage**

**Drug Facts (continued)**  
 ■ cough that occurs with too much phlegm (mucus) thinning drug warfarin  
 ■ Ask a doctor or pharmacist before use if you are taking the blood

**Drug Facts**

**Active ingredients (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

**Drug Facts (continued)**  
 ■ temporarily reduces fever  
 ■ helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive  
 ■ 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

**Uses** ■ for the temporary relief of the following cold/flu symptoms:  
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 ■ nasal congestion ■ cough  
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NDC 63868-003-24



'Compare to **TYLENOL**® Cold & Flu Severe active ingredients

# Severe Cold & Flu For Adults

Pain Reliever | Fever Reducer, Nasal Decongestant, Cough Suppressant, Expectorant

Acetaminophen, Phenylephrine HCl, Dextromethorphan HBr, Guaifenesin

**For Relief of:**  
 Headache | Fever | Sore Throat  
 Nasal Congestion  
 Cough | Chest Congestion  
 Clears Out Mucus



**24** Cool Taste Caplets

SEE NEW WARNINGS INFORMATION & DIRECTIONS

**Drug Facts (continued)**

**Other information**  
 ■ store between 20-25°C (68-77°F) in a dry place  
 ■ retain carton for complete product information

**Inactive ingredients**  
 silicon dioxide, corn starch, croscarmellose sodium, crospovidone, acsulfurame potassium, colloidal

**Drug Facts (continued)**  
 D&C yellow #10, FD&C blue #2, flavor, magnesium stearate, maitodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

Distributed by C.D.M.A., Inc.  
 43157 W. Nine Mile  
 Novi, MI 48376-0995  
 www.qualitychoice.com  
 Questions: 248-449-9300

This product is not manufactured or distributed by McKellic Consumer Healthcare, distributor of Tylenol® Cold & Flu Severe.

DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN

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

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63868-003
<b>Route of Administration</b>	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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (UNII: 68401960MK)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	yellow	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>	MINT	<b>Imprint Code</b>	AAA;1136
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-003-24	2 in 1 CARTON	07/24/2012	

1	12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part341	07/24/2012	

**Labeler** - Chain Drug Marketing Association (011920774)

Revised: 12/2018

Chain Drug Marketing Association