

COLD FLU SEVERE- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, coated
STRATEGIC SOURCING SERVICES LLC

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.

SMK - 1163 - 2020-0603

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

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.

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">▪ 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	<ul style="list-style-type: none">▪ ask a doctor

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

PRINCIPAL DISPLAY PANEL

sunmark(R)

Compare to Tylenol(R) Cold + FLu Severe active ingredients

NDC 70677-0100-1

cold + flu severe

Head + Body Aches, Fever + Sore Throat, Cough + Nasal Congestion, Mucus + Chest Congestion

Acetaminophen, Phenylephrine HCl, Dextromethorphan HBr, Guaifenesin

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

Actual Size

COOL TASTE INSTANT COOLING SENSATION

For Adults

24 CAPLETS



F116305SMK_R1

Drug Facts (continued)

Other information

- store between 20-25°C (68-77°F) in a dry place
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Inactive ingredients

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Drug Facts (continued)

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

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 using this product

■ Acetaminophen may cause severe skin reactions

■ Allergy alert: Acetaminophen may cause severe skin reactions

Symptoms may include: ■ skin redness ■ hives ■ rash ■ skin redness ■ hives ■ rash ■ skin redness ■ hives ■ 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.
- 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.
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Drug Facts (continued)

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- swallow whole – do not crush, chew, or dissolve
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children under 12 years

- ask a doctor

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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:

- redness or swelling is present
- 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

- When using this product do not exceed recommended dosage
- Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

Drug Facts (continued)

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COMPARE TO TYLENOL® COLD + FLU SEVERE ACTIVE INGREDIENTS† NDC 70677-0100-1

sunmark® cold + flu severe

Head + Body Aches, Fever + Sore Throat, Cough + Nasal Congestion, Mucus + Chest Congestion

Acetaminophen, Phenylephrine HCl, Dextromethorphan HBr, Guaifenesin

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

Actual Size

COOL TASTE INSTANT COOLING SENSATION

For Adults **24 CAPLETS**

MEKESON

Another Quality Product Distributed By Mekesson 6555 State Highway 161, Irving, TX 75039 Money Back Guarantee Please visit us at www.sunmarkbrand.com

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

DO NOT USE IF BUSTLER UNITS ARE TORN OR BROKEN

NC

NC

NC

COLD FLU SEVERE

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70677-0100
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
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, UNSPECIFIED (UNII: 2S7830E561)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677-0100-1	2 in 1 CARTON	06/03/2020	06/30/2024
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 final	part341	06/03/2020	06/30/2024

Labeler - STRATEGIC SOURCING SERVICES LLC (116956644)

Revised: 11/2022

STRATEGIC SOURCING SERVICES LLC