SUNMARK COLD AND FLU SEVERE- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film 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.

McKesson Cold & Flu Severe Drug Facts

Active ingredients (in each caplet)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

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. 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	• 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

- **each caplet contains:** sodium 3 mg

Inactive ingredients

acesulfame potassium, carnauba wax, croscarmellose sodium, crospovidone, D&C yellow #10 aluminum lake, flavor, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, silicon dioxide, stearic acid, talc, titanium dioxide

Questions or comments?

1-800-719-9260

Principal Display Panel

COMPARE TO TYLENOL® COLD + FLU SEVERE ACTIVE INGREDIENTS

cold & flu

Severe

Pain Reliever, Fever Reducer

Nasal Decongestant

Cough Suppressant, Expectorant

Headache/Sore Throat – Acetaminophen

Nasal Congestion – Phenylephrine HCl

Coughing – Dextromethorphan HBr

Chest Congestion – Guaifenesin

FOR ADULTS

Actual Size

GLUTEN FREE

24 CAPLETS

Important: Read all product information before using.
Keep this box for important information.

DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN

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

PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

sunmark®

COMPARE TO TYLENOL® COLD + FLU SEVERE ACTIVE INGREDIENTS*

NDC 49348-104-04

cold & flu
Severe

Pain Reliever, Fever Reducer
Nasal Decongestant
Cough Suppressant, Expectorant

Headache/Sore Throat • **Acetaminophen**
Nasal Congestion • Phenylephrine HCl
Coughing • Dextromethorphan HBr
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Actual Size

FOR ADULTS

GLUTEN FREE

24 CAPLETS

23462 S1 C7

Drug Facts

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Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
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Uses ■ for the temporary relief of the following cold/flu symptoms: ■ minor aches and pains ■ headache ■ sore throat ■ cough ■ nasal congestion ■ helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive ■ temporarily reduces fever

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Drug Facts (continued)

Ask a doctor before use if you have ■ liver disease ■ diabetes ■ high blood pressure ■ thyroid disease ■ heart disease ■ 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

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Drug Facts (continued)

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Drug Facts (continued)

Questions or comments? 1-800-719-9260

Store at 20-25°C (68-77°F).

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McKESSON

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

SUNMARK COLD AND FLU SEVERE

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49348-104
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: 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)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

Product Characteristics			
Color	YELLOW	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	L234
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49348-104-04	12 in 1 CARTON	03/19/2008	
1		2 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	03/19/2008	

Labeler - Strategic Sourcing Services LLC (116956644)

Revised: 2/2020 Strategic Sourcing Services LLC