MUCUS RELIEF COLD FLU AND SORE THROAT- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, coated Meijer

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.

1197-MEI-2021-0219

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

- temporarily relieves these common cold and flu symptoms:
 - nasal congestion
 - headache
 - cough
 - minor aches and pains
 - sore throat
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 12 caplets in 24 hours, which is the maximum daily amount
- 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 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
- diabetes
- high blood pressure
- thyroid 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

When using this product do not use more than directed

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

Taking more than the recommended dose (overdose) may cause liver damage. 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)
- do not take more than 12 caplets in any 24-hour period
- adults and children 12 years of age and older: take 2 caplets every 4 hours
- children under 12 years of age: do not use

Other information

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

Inactive ingredients

colloidal silicon dioxide, corn starch, croscarmellose sodium, crospovidone, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

Questions or comments?

1-844-705-4384

PRINCIPAL DISPLAY PANEL

NDC 41250-197-04

Compare to Mucinex ® Fast-Max ® Cold, Flu & Sore Throat active ingredients†

Meijer ®

For Ages 12+

MAXIMUM STRENGTH

mucus relief cold, flu & sore throat

Acetaminophen | Dextromethorphan HBr

Guaifenesin | Phenylephrine HCl

Pain Reliever/Fever Reducer, Cough Suppressant,

Expectorant, Nasal Decongestant

Relieves Headache, Fever & Sore Throat; Controls Cough;

Relieves Nasal & Chest Congestion; Thins & Loosens Mucus

20 CAPLETS

actual size



MUCUS RELIEF COLD FLU AND SORE THROAT

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

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:412	50-197
Route of Administration	ORAL				
A ative transations (A ative	Malater				
Active Ingredient/Active	мојету				
Ingree	dient Name		Basis of Str	ength	Strength
ACETAMINOPHEN (UNII: 36209ITL	9D) (ACETAMINOPHEN - UN	I:362O9ITL9D)	ACETAMINOPHEN		325 mg
DEXTROMETHORPHAN HYDROB (DEXTROMETHORPHAN - UNII:7355X	•)	DEXTROMETHORP HYDROBROMIDE	HAN	10 mg
GUAIFENESIN (UNII: 495W7451VQ)) (GUAIFENES IN - UNII:495W	7451VQ)	GUAIFENESIN		200 mg
PHENYLEPHRINE HYDROCHLORI UNII:1WS297W6MV)	DE (UNII: 04JA59TNSJ) (PHE	NYLEPHRINE -	PHENYLEPHRINE HYDROCHLORIDE		5 mg
Inactive Ingredients					
	Ingredient Name			S	trength

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SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C RED NO. 40 (UNII: WZ B9127XOA)	
ALUMINUM OXIDE (UNII: LMI2606933)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: 08232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	AAA;1165
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:41250- 197-02	2 in 1 CARTON	09/01/2019	08/31/2022
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
/	NDC:41250- 197-04	2 in 1 CARTON	02/01/2021	
		10 in 1 PACKAGE; Type 0: Not a Combination		
2		Product		
		••		
		Product	Marketing Start Date	Marketing End Date

Labeler - Meijer (006959555)