

MEDIQUE COLD COUGH PRODUCT- acetaminophen, dextromethorphan hbr, phenylephrine hcl , tablet, film coated
Unifirst First Aid Corporation

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.

Medique Cold & Cough

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine Hydrochloride 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

temporarily relieves these common cold/flu symptoms:

- minor aches and pains
 - headache
 - sore throat
 - nasal congestion
 - cough
 - sinus congestion and pressure
 - 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 12 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: acetaminophen may cause a severe skin reactions. Symptoms may include:

- skin reddening
- blisters

- rash

If a skin reaction occurs, stop use and seek medical help immediately.

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 drugs. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist.

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, 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 gets worse or lasts for 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 accidental overdose, contact a doctor or Poison Control Center (1-800-222-1222) immediately. Taking more than the recommended dose (overdose) may cause liver damage. 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 **Warnings**)

Adults and children: (12 years and over)

- take 2 caplets every 4 hours
- do not take more than 12 caplets in 24 hours

Children under 12 years: do not use this adult product in children under 12 years of age. This will provide more than the recommended dose (overdose) and may cause liver damage.

Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- tamper evident sealed packets
- do not use any opened or torn packets

Inactive ingredients

colloidal silicon dioxide, corn starch, croscarmellose sodium, crospovidone, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, silicon dioxide, stearic acid, titanium dioxide

Questions or comments? 1-800-634-7680

Medique®

Cold & Cough Product

Multi-Symptom Relief

Pull to Open

Pain Reliever/Fever Reducer • Acetaminophen 325 mg

Cough Suppressant • Dextromethorphan HBr 10 mg

Nasal Decongestant • Phenylephrine HCl 5 mg

80 Caplets

(40 x 2)

Tamper Evident Unit Dose Packets



MEDIQUE COLD COUGH PRODUCT

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:47682-108
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPVIDONE (UNII: 2S7830E561)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE (Caplet)	Size	17mm
Flavor		Imprint Code	AZ;324
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47682-108-80	40 in 1 BOX	09/26/2022	
1	NDC:47682-108-99	2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:47682-108-36	75 in 1 BOX	12/12/2022	
2		2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	09/26/2022	

Labeler - Unifirst First Aid Corporation (832947092)

Revised: 12/2022

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