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

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### **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
- $\blacksquare$  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

 $(40 \times 2)$ 

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	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients	
Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPOVIDONE (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				

P	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		
3	NDC:47682-108- 99	2 in 1 PACKET; Type 0: Not a Combination Product	09/26/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	09/26/2022	

## Labeler - Unifirst First Aid Corporation (832947092)

Revised: 9/2024 Unifirst First Aid Corporation