MEDIQUE AT HOME COLD RELIEF- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride tablet 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 @ Home Cold Relief

Drug Facts

Active ingredients (in each tablet)

Acetaminophen 325 mg

Dextromethorphan Hydrobromide 15 mg

Guaifenesin 200 mg

Phenylephrine Hydrochloride 5 mg.

Purpose

Pain reliever/ fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Uses

- for the temporary relief of the following cold/flu symptoms:
- \blacksquare minor aches and pains \blacksquare headache \blacksquare sore throat \blacksquare nasal congestion \blacksquare 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 tablets (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
- for more than 10 days unless directed by a doctor

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 that lasts 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 dose

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion or cough gets worse or lasts for more than 7 days
- fever gets worse or lasts for 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 children12 years and older

- take 2 tablets every 6-8 hours
- swallow whole; do not crush, chew or dissolve
- do not take more than 8 tablets in 24 hours

Children under 12 years

ask a doctor

Other information

- store at room temperature 68°-77°F (20°-25°C)
- keep this product protected from extremes of moisture, heat and light
- Tamper Evident child resistant packets
- do not use any opened or torn packets

Inactive ingredients

maltodextrin, microcrystalline cellulose, povidone, silicon dioxide, sodium starch glycolate, starch, stearic acid

Questions or comments? 1-800-634-7680

Medique® @ Home

Multi-Symptom Cold Relief

Acetaminophen 325 mg • Pain Reliever/ Fever Reducer

Dextromethorphan Hydrobromide 15 mg • Cough Suppressant

Guaifenesin 200 mg • Expectorant

Phenylephrine Hydrochloride 5 mg • Nasal Decongestant

Pull to Open

Child-Resistant Packets

50 Packets

(2 Tablets Per Packet)





MEDIQUE AT HOME COLD RELIEF

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride tablet

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:47682-725 Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg	

Inactive Ingredients		
Ingredient Name	Strength	
STARCH, CORN (UNII: O8232NY3SJ)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
MALTODEXTRIN (UNII: 7CVR7L4A2D)		
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)		

SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)

Product Characteristics				
Color	white	Score	no score	
Shape	ROUND	Size	12mm	
Flavor		Imprint Code	FR;12	
Contains				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:47682-725- 33	50 in 1 BOX	02/01/2021			
1		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 final	part341	02/01/2021		

Labeler - Unifirst First Aid Corporation (832947092)

Revised: 3/2022 Unifirst First Aid Corporation