MUCUS RELIEF DM EXTENDED RELEASE CAPLETS- guaifenes in, dextromethorphan hbr tablet

Cardinal Health (Leader) 70000

Drug Facts

Active ingredients (in each extended-release tablet)

Dextromethorphan HBr 60 mg

Guaifenesin 1200 mg

Purpose

Cough Suppressant

Expectorant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves
 - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
 - the intensity of coughing
 - the impulse to cough to help you get to sleep

Warnings

Do not use

- for children under 12 years of age
- 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

- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough accompanied by too much phlegm (mucus)

When using this product,

do not use more than directed.

Stop use and ask a doctor if

cough lasts more than 7 days, comes back, or occurs with fever, rash or persistent headache. These could be signs of a serious illness.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- do not crush, chew, or break tablet
- take with a full glass of water
- this product can be administered without regards for timing of meals
- adults and children 12 years of age and older: 1 tablet every 12 hours; not more than 2 tablets in 24 hours
- children under 12 years of age: do not use

Other information

• store between 20° to 25°C (68° to 77°F)

Inactive ingredients

carbomer, colloidal silicon dioxide, D&Cyellow #10 aluminum lake, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, talc

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

COMPARE TO MUCINEX® DM MAXIMUM STRENGTH active ingredients*

Maximum strength

Mucus Relief DM

Dextromethorphan HBr, 60 mg

Guaifenesin, 1200 mg

Cough Suppressant Expectorant

12 Hour Relief

Controls Cough

Thins and Loosens Mucus

EXTENDED-RELEASE TABLETS

*This product is not manufactured or distributed Reckitt Benckiser LLC, distributor Mucinex® DM Maximum Strength.

TAMPER EVIDENT: DO NOT USE IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 43017

www.myleader.com

Package Label



LEADER Maximum Strength Mucus Relief DM

MUCUS RELIEF DM EXTENDED RELEASE CAPLETS

guaifenesin, dextromethorphan hbr tablet

(DEXTROMETHORPHAN - UNII:7355X3ROTS)

DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH)

GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)

guarenesii, dexirometrorphan nor tablet					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (So	urce)	NDC:70000-04	64
Route of Administration	ORAL				
Active Ingredient/Active Moiety					
Ingredient Name		Basis of S	Strength	Strength	

DEXTROMETHORPHAN

HYDROBROMIDE

GUAIFENES IN

60 mg

1200 mg

Inactive Ingredients	
Ingredient Name	Strength

CARBOMER 934 (UNII: Z135WT9208)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
PO VIDO NE (UNII: FZ989 GH94E)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristic	roduct Characteristics			
Color	YELLOW	Score	no score	
Shape	OVAL	Size	22mm	
Flavor		Imprint Code	AN039	
Contains				

I	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:70000-0464-1	28 in 1 CARTON	12/31/2018		
1		$1\ \text{in}\ 1\ \text{BLISTER}$ PACK; Type 0: Not a Combination Product			
2	NDC:70000-0464-2	14 in 1 CARTON	12/31/2018		
2		1 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	
ANDA	ANDA209692	12/31/2018		

Labeler - Cardinal Health (Leader) 70000 (097537435)

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