MUCUS RELIEF DM- guaifenes in and dextromethorphan hydrobromide capsule, liquid filled Walgreens

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.

MUCUS RELIEF DM

Drug Facts

Active ingredient (in each softgel)	Purposes
Guaifenesin 400mg	Expectorant
Dextromethorphan HBr 20mg	Cough Suppressant

Uses

- helps loosen phlegm (mucus)
- helps thin bronchial secretions to make coughs more productive

Warnings

Do not use

• 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 Doctor before use if you have

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

When using this product

- do not exceed recommended dosage
- do not use for more than 7 days

Stop use and ask a doctor if

• cough lasts for more than 7 days, recurs, or is accompanied by fever, rash, or persistent headache. 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, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 12 years of age and older:

- Take with a full glass of water.
- Take 1 softgel every 4 hours with a full glass of water while symptoms persist. Do not exceed 6 doses in 24 hours.
- Children under 12 years of age: do not use

Other information

- store at 25°C (77°F) excursions between 15° 30°C (59° 86°F)
- keep in a dry place and do not expose to heat
- you may report side effects to 1-888-333-9792

Inactive Ingredients

FD&C Yellow #10, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide

Questions or comments?

1-888-333-9792

PRINCIPAL DISPLAY PANEL - 30 Softgels Blister Pack Carton

NEW

Well at

Walgreens

NDC 0363-9891-30

WALGREENS PHARMACIST RECOMMENDED[‡]

Mucus

Relief DM

DM Cough

Guaifenes in 400 mg / Expectorant Dextromethorphan HBr 20 mg / Cough Suppressant

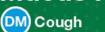
- Controls cough
- Thins & loosens mucus
- Easy to swallow

30 SOFTGELS

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Mucus Relief DM



Guaifenesin 400 mg / Expectorant Dextromethorphan HBr 20 mg / **Cough Suppressant**

WALGREENS PHARMACIST RECOMMENDED

Mucus



NDC 0363-9891-30

WALGREENS PHARMACIST RECOMMENDED

Relief DM



Guaifenesin 400 mg / Expectorant Dextromethorphan HBr 20 mg / **Cough Suppressant**

- Controls cough
- Thins & loosens mucus
- Easy to swallow

 $30_{\sf softgels}$



LOT NO: EXP DATE:

Questions or comments? 1-888-333-9792

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Drug Facts (continued)

THIS PRODUCT IS PACKAGED IN A CHILD-RESISTANTAND
TAMPER-EWIDENT PACKAGE. USE ONLY I FBLISTER'S A REI NTACT.

ORG0515-F

^tWalgreensPharmacist Survey Study, November2014

MUCUS RELIEF DM

guaifenesin and dextromethorphan hydrobromide capsule, liquid filled

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-9891	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg	
DEXTRO METHO RPHAN HYDRO BRO MIDE (UNII: 9 D2RTI9 KYH) (DEXTRO METHO RPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg	

Inactive Ingredients			
Ingredient Name	Strength		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
GELATIN (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)			
PO VIDO NES (UNII: FZ989 GH94E)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			

Product Characteristics			
Color	YELLOW	Score	no score
Shape	OVAL (OBLONG)	Size	20 mm
Flavor		Imprint Code	440
Contains			

	Packaging			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:0363-9891- 30	3 in 1 CARTON		
l	1	10 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
OTC monograph final	part341	08/15/2015	

Labeler - Walgreens (008965063)

Registrant - Spirit Pharmaceuticals LLC (179621011)

Establishment			
Name	Address	ID/FEI	Business Operations
MEDGEL PVT LTD		677385498	MANUFACTURE(0363-9891)

Revised: 8/2015 Walgreens