

GUAIFENESIN DM- guaifenesin and dextromethorphan hydrobromide syrup

Physicians Total Care, Inc.

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.

Q-Tussin DM 0855

Active ingredients (in each 5 mL = 1 tsp)

Dextromethorphan HBr, USP 10 mg

Guaifenesin, USP 100 mg

Purpose

Cough suppressant

Expectorant

Uses

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes

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 a doctor before use if you have

- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema

Stop use and ask a doctor if cough lasts more than 7 days, comes back 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 overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not take more than 6 doses in any 24-hour period
- this adult product is not intended for use in children under 12 years of age

age (yr)	dose (tsp)
adults and children 12 years and over	2 teaspoons every 4 hours
children under 12 years	do not use

Other information

- store at 15° to 30°C (59° to 86°F)
- dosage cup provided

You may report serious side effects to: *130 Vintage Drive, Huntsville, AL 35811.*

Inactive ingredients

citric acid, FD&C red #40, flavors, glycerin, high fructose corn syrup, liquid glucose, purified water, saccharin sodium, sodium benzoate

Made in the **USA**
for Qualitest Pharmaceuticals
Huntsville, AL 35811

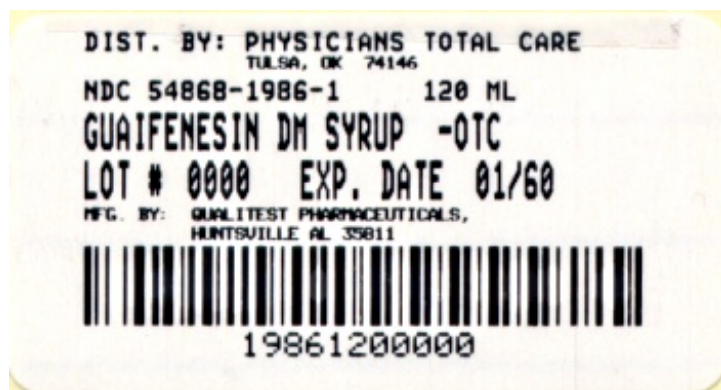
Rev. 7/09 R4
8281171 0855

Additional barcode labeling by:

Physicians Total Care, Inc.
Tulsa, Oklahoma 74146

PRINCIPAL DISPLAY PANEL

NDC 54868-1986-1
118 mL



GUAIFENESIN DM

guaifenesin and dextromethorphan hydrobromide syrup

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-1986(NDC:0603-0855)
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 in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

Inactive Ingredients	
Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
GLUCOSE OXIDASE (UNII: 0T8392U5N1)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Product Characteristics			
Color	RED (clear, red)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-1986-0	473 mL in 1 BOTTLE, PLASTIC		
2	NDC:54868-1986-1	118 mL in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	11/16/1999	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		19 4123980	relabel

Revised: 3/2012

Physicians Total Care, Inc.