# GILTUSS DIABETIC DM- dextromethorphan hbr solution Gil Pharmaceutical Corp

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Giltuss Diabetic DM Dextromethorphan HBr, 30 mg Maximum Strength

## **Drug Facts**

## Active Ingredient (In each 10 mL)

**Purpose** 

Dextromethorphan HBr. 30 mg ...... Cough Suppresant

### Uses

- temporarily relieves:
  - cough due to minor throat and bronchial irritation associated with a common cold or inhaled irritants
  - the intensity of coughing
  - the impulse to cough to help you get to sleep

## 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.
- When using this product do not use more than directed.

## Ask a doctor before use if you have

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

## Stop use and ask a doctor if

cough lasts for more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache as 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 exceed recommended dosage
- do not take more than 4 doses in any 24-hour period

- use enclosed dosing cup
- mL= milliliter

Adults and children over 12	
years	8 hours
Children under 6 years to	5 mL every 8
under 12 years	hours
Children 4 years to under 6	2.5 mL *every
years	8 hours
Children under 4 years	Do not use

<sup>\*</sup> use appropriate measuring syringe or measuring cup

### Other information

- store at room temperature 15°-30°C (59°-86°F)
- close cap tightly
- SAVE CARTON FOR COMPLETE DRUG FACTS

## **Inactive ingredients**

Acesulfame potassium, citric acid, flavor, glycerin, menthol, polyethylene glycol, povidone, propylene glycol, purified water, sodium benzoate, sodium saccharin.

## Questions or comments?

Call **1-787-848-9114,** Monday-Friday 9AM-5PM EST.

Call your doctor for medical advice in the event of side effects.

### **MANUFACTURED FOR**

GIL PHARMACEUTICAL CORP. PONCE, PUERTO RICO 00717-1565

### PRINCIPAL DISPLAY PANEL

Giltuss Diabetic DM - NDC 58552-149-04 - Bottle Label

#### **Drug Facts**

Active ingredient (in each 10 mL) Purpose Dextromethorphan HBr. 30 mg\_\_\_\_\_ "Cough Suppresant

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#### Drug Facts (continued).

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2.5 mL* every 8 hours
Do not use

\* use appropriate measuring syringe or measuring cup

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Label revised: 02/23

Giltuss Diabetic DM - NDC 58552-149-04 - Carton Label



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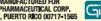
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PERSONS WITH DIJABETES: CONSULT YOUR DOCTOR OR PHARMACIST BEFORE USING ANY MEDICATION OR DIETARY SUPPLEMENT THIS PRODUCT DOES NOT CONTAIN ANY MEDICATION TO IMPROVE OR RELIEVE DIABETES



MANUFACTURED FOR GIL PHARMACEUTICAL CORP. PONCE, PUERTO RICO 00717-1565



#### Drug Facts (continued).

#### Directions

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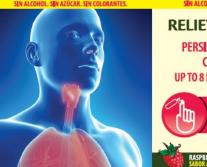
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Label revised: 02/23

ALCOHOL FREE. SUGAR FREE. DYE FREE.





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## **RELIEVES ALIVIA**

PERSISTENT ✓ TOS COUGH PERSISTENTE UP TO 8 HOURS HASTA POR 8 HORAS

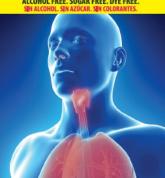




**UP TO 8 HOURS** 

**FUERZA ANTITUSIVA PARA** CONTROLAR LA TOS HASTA POR 8 HORAS

ALCOHOL FREE. SUGAR FREE. DYE FREE.



## GILTUSS DIABETIC DM

dextromethorphan hbr solution

### **Product Information**

NDC:58552-149 HUMAN OTC DRUG **Product Type** Item Code (Source)

**Route of Administration ORAL** 

## **Active Ingredient/Active Moiety**

**Ingredient Name Basis of Strength** Strength **DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) DEXTROMETHORPHAN** 30 mg (DEXTROMETHORPHAN - UNII:7355X3ROTS) **HYDROBROMIDE** in 10 mL

**Inactive Ingredients** 

Ingredient Name	Strength
POVIDONE (UNII: FZ 989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL (UNII: L7T10EIP3A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics			
Color			
Shape		Size	
Flavor	RASPBERRY	Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58552-149- 04	1 in 1 CARTON	08/09/2023	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	08/09/2023	

# **Labeler -** Gil Pharmaceutical Corp (176826592)

Establishment			
Name	Address	ID/FEI	Business Operations
SEAWAY PHARMA		117218785	analysis(58552-149), manufacture(58552-149), pack(58552-149)

Revised: 10/2023 Gil Pharmaceutical Corp