

GILTUSS DIABETIC DM- dextromethorphan hbr solution
Gil Pharmaceutical Corp

Giltuss Diabetic DM
Dextromethorphan HBr, 30 mg
Maximum Strength

Drug Facts

Active Ingredient (In each 10 mL)

Purpose

Dextromethorphan HBr. 30 mg Cough Suppressant

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	10 mL every 8 hours
Children under 6 years to under 12 years	5 mL every 8 hours
Children 4 years to under 6 years	2.5 mL * every 8 hours
Children under 4 years	Do not use

* 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 Suppressant

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.

MAXIMUM STRENGTH. MÁXIMA CONCENTRACIÓN.

ALCOHOL FREE.
SUGAR FREE.
DYE FREE.

SIN ALCOHOL.
SIN AZÚCAR.
SIN COLORANTES.



Giltuss
DIABETIC
DM

8hr Cough
TOS
Dextromethorphan HBr, 30 mg

RELIEVES
PERSISTENT COUGH UP TO 8 HOURS
ALIVIA
TOS PERSISTENTE HASTA POR 8 HORAS



SAFE FOR PEOPLE
WITH DIABETES
SEGURO PARA PERSONAS CON DIABETES

4FL OZ (118 mL)

RASPBERRY FLAVOR.
SABOR A FRAMBUESA.



Drug Facts (continued).

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	10 mL every 8 hours
Children under 6 years to under 12 years	5 mL every 8 hours
Children 4 years to under 6 years	2.5 mL* every 8 hours
Children under 4 years	Do not use

* 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

Acetulfame 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

giltuss.com
Label revised: 02/23

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

Drug Facts

Active ingredient (in each 10 mL) Purpose
Dextromethorphan HBr, 30 mg...Cough Suppressant

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.

PERSONS WITH DIABETES: 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

giltuss.com

Drug Facts (continued).

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	10 mL every 8 hours
Children under 6 years to under 12 years	5 mL every 8 hours
Children 4 years to under 6 years	2.5 mL* every 8 hours
Children under 4 years	Do not use

* 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.
Label revised: 02/23

*Tamperevidente: do not use if safety seal under or around the cap is broken or missing.

DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING.
NO LO USE SI LA TIRILLA EN LA TAPA ESTÁ ROTA O FALTA.



**ANTITUSSIVE
ANTITUSIVO**

**MAXIMUM STRENGTH
MÁXIMA CONCENTRACIÓN**



**Giltuss
DIABETIC
DM**



**8hr Cough
TOS**
Dextromethorphan HBr, 30 mg

**ALCOHOL FREE. SUGAR FREE. DYE FREE.
SIN ALCOHOL. SIN AZÚCAR. SIN COLORANTES.**

RELIEVES ALIVIA

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



**SAFE FOR PEOPLE
WITH DIABETES**
SEGURO PARA PERSONAS CON DIABETES

RASPBERRY FLAVOR.
SABOR A FRAMBUESA.

**4FL OZ
(118 mL)**

**Giltuss
DIABETIC
DM**



**8hr Cough
TOS**
Dextromethorphan HBr, 30 mg

**ANTITUSSIVE STRENGTH
TO CONTROL COUGH
SYMPTOMS
UP TO 8 HOURS**

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

**ALCOHOL FREE. SUGAR FREE. DYE FREE.
SIN ALCOHOL. SIN AZÚCAR. SIN COLORANTES.**

GILTUSS DIABETIC DM

dextromethorphan hbr solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58552-149
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL (UNII: L7T10EIP3A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	RASPBERRY	Imprint Code	
Contains			

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