

GILTUSS DM- dextromethorphan hbr syrup
Gil Pharmaceutical Corp

Giltuss[®] DM High Blood Pressure
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.

Label revised: 02/23

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

PRINCIPAL DISPLAY PANEL

Giltuss DM High Blood Pressure - NDC 58552-150-04 - Bottle Label

Drug Facts

Active ingredient (in each 10 mL) *Purpose*

Dextromethorphan HBr, 30 mg.....Cough Suppressant

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MAXIMUM STRENGTH. MÁXIMA CONCENTRACIÓN.

ALCOHOL FREE.
SUGAR FREE.
DYE FREE.

SIN ALCOHOL.
SIN AZÚCAR.
SIN COLORANTES.



HIGH BLOOD PRESSURE HBP
Giltuss
DM

8hr Cough
TOS
Dextromethorphan HBr, 30 mg

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



NASAL DECONGESTANT FREE
SAFE FOR PEOPLE WITH
HIGH BLOOD PRESSURE
SEGURO PARA PERSONAS CON PRESIÓN ALTA

SIN DESCONGESTIVOS NASAL

4FL OZ (118 mL)

RASPBERRY FLAVOR.
SABOR A FRAMBUESA.



Drug Facts (continued).

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PONCE, PUERTO RICO 00717-1565

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Label revised: 02/23

Giltuss DM High Blood Pressure - NDC 58552-150-04 - Carton Label

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Label revised: 02/23

Tamper evident: 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 TAPILLA EN LA TAPA ESTA ROTA O FALTA.

ANTITUSSIVE
ANTITUSIVO

MAXIMUM STRENGTH
MÁXIMA CONCENTRACIÓN

HIGH BLOOD PRESSURE HBP
Giltuss
DM

8hr Cough TOS
Dextromethorphan HBr, 30 mg

HIGH BLOOD PRESSURE HBP
Giltuss
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.

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

NASAL DECONGESTANT FREE
SAFE FOR PEOPLE WITH HIGH BLOOD PRESSURE
SEGURO PARA PERSONAS CON PRESIÓN ALTA
SIN DESCONGESTIONANTE NASAL

RASPBERRY FLAVOR.
SABOR A FRAMBUESA.

4FL OZ (118 mL)

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

GILTUSS DM			
dextromethorphan hbr syrup			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58552-150
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

ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
RASPBERRY (UNII: 4N14V5R27W)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL (UNII: L7T10EIP3A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics

Color	white (clear color)	Score	
Shape		Size	
Flavor	RASPBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58552-150-04	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	06/27/2023	

Labeler - Gil Pharmaceutical Corp (176826592)

Revised: 12/2023

Gil Pharmaceutical Corp