

GILTUSS HONEY DM COUGH- dextromethorphan hbr solution
Gil Pharmaceutical Corp

Giltuss Honey DM

Drug Facts

Active ingredient (in each 10 mL)

Dextromethorphan HBr, 30 mg

Purposes

Cough Suppressant

Uses

- temporarily relieves:
- cough due to minor throat and bronchial irritation associated with the common cold or inhaled irritants
- the intensity of coughing
- the impulse to cough to help your child 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.

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. 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 4 doses in any 24-hour period
- use enclosed dosing cup
- **keep dosage cup for use with this product**
- ml = milliliters

| | |
|---------------------------------------|------------------------|
| adults and children 12 years and over | 10 mL every 6-8 hours |
| children 6 to under 12 years of age | 5 mL every 6-8 hours |
| children 4 to under 6 years of age | 2.5 mL every 6-8 hours |

children under 4 years of age

Consult a doctor

Other information

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

Inactive ingredients natural and artificial flavor, natural grade A honey, methylparaben, potassium sorbate, propylene glycol, propylparaben, purified water, sucralose.

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.

Tamper Evident: do not use if safety seal is broken or missing.

MANUFACTURED FOR

GIL PHARMACEUTICAL CORP.

PONCE, PUERTO RICO 00717-1565

giltuss.com

MAXIMUM STRENGTH

Giltuss®

Honey DM Cough

Made with real honey

ALCOHOL FREE. DYE FREE. NON-DROWSY

RELIEVES

PERSISTENT COUGH UP TO 8 HOURS

HONEY LEMON FLAVOR.

4FL OZ (118 mL)



GILTUSS HONEY DM COUGH

dextromethorphan hbr solution

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58552-143 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

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

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| WATER (UNII: 059QF0KO0R) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| HONEY (UNII: Y9H1V576FH) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |

Product Characteristics

| | | | |
|-----------------|-----------------------|---------------------|--|
| Color | yellow (Light yellow) | Score | |
| Shape | | Size | |
| Flavor | HONEY, LEMON | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:58552-143-04 | 1 in 1 CARTON | 06/22/2020 | |
| 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 | 06/22/2020 | |

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

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|------------------------|
| Dextrum Laboratories Inc | | 007392322 | manufacture(58552-143) |