

**ROBITUSSIN HONEY MAXIMUM STRENGTH NIGHTTIME COUGH DM-
dextromethorphan hbr, doxylamine succinate solution
GlaxoSmithKline Consumer Healthcare Holdings (US) LLC**

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.

Drug Facts

Active ingredients (in each 20 ml)

Dextromethorphan HBr, USP 30 mg

Doxylamine Succinate, USP 12.5 mg

Purposes

Cough suppressant

Antihistamine

Uses

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
 - o runny nose
 - o sneezing
 - o itchy, watery eyes
 - o itching of the nose or throat
- controls the impulse to cough to help you sleep

Warnings

Do not use

- to sedate a child or to make a child sleepy
- 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

- trouble urinating due to an enlarged prostate gland
- glaucoma
- a cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product

- **do not use more than directed**
- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

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

- measure only with dosing cup provided
- keep dosing cup with product
- ml = milliliter
- do not take more than 4 doses in any 24-hour period
- this adult product is not intended for use in children under 12 years of age

| age | dose |
|---------------------------------------|---------------------|
| adults and children 12 years and over | 20 ml every 6 hours |
| children under 12 years | do not use |

Other information

- each 20 ml contains: **sodium 21 mg**
- store at 20-25°C (68-77°F)

Inactive ingredients

anhydrous citric acid, blueberry juice concentrate, carboxymethylcellulose sodium, glycerin, lactic acid, natural and artificial flavors, natural grade A honey, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium

gluconate, sucralose, xanthan gum, zinc gluconate

Questions or comments?

call weekdays from 9 AM to 5 PM EST at **1-800-762-4675**

Distributed by: Pfizer, Madison, NJ 07940 USA

PRINCIPAL DISPLAY PANEL

ADULT

NEW!

Robitussin®

Honey

**Nighttime
Cough DM**

DEXTROMETHORPHAN HBr (Cough Suppressant)

DOXYLAMINE SUCCINATE (Antihistamine)

MAXIMUM STRENGTH

1. Controls Cough
2. Relieves runny nose and sneezing

Taste the

Real Honey

DM

NIGHTTIME

MAX

For Ages 12+

4 FL OZ (118 ml)



ROBITUSSIN HONEY MAXIMUM STRENGTH NIGHTTIME COUGH DM

dextromethorphan hbr, doxylamine succinate solution

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0031-8758 |
| 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 20 mL |
| DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII: 95QB77JKPL) | DOXYLAMINE SUCCINATE | 12.5 mg in 20 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |
| CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |

| |
|--|
| LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT) |
| HONEY (UNII: Y9H1V576FH) |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A) |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) |
| WATER (UNII: 059QF0KO0R) |
| SODIUM BENZOATE (UNII: OJ245FE5EU) |
| SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR) |
| SODIUM GLUCONATE (UNII: R6Q3791S76) |
| SUCRALOSE (UNII: 96K6UQ3ZD4) |
| XANTHAN GUM (UNII: TTV12P4NEE) |
| ZINC GLUCONATE (UNII: U6WSN5SQ1Z) |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | BERRY | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0031-8758-12 | 1 in 1 CARTON | 06/25/2018 | |
| 1 | | 118 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package | | |
| 2 | NDC:0031-8758-18 | 1 in 1 CARTON | 06/25/2018 | |
| 2 | | 237 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | 06/25/2018 | |

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------------|---------|-----------|---|
| PF Consumer Healthcare Canada ULC | | 203812479 | ANALYSIS(0031-8758) , LABEL(0031-8758) , MANUFACTURE(0031-8758) , PACK(0031-8758) |