CHILDRENS ROBITUSSIN HONEY 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 10 ml)	***Purposes***
Dextromethorphan HBr, USP 15 mg	Cough suppressant
Doxylamine Succinate, USP 6.25 mg	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:
    - runny nose
    - sneezing
    - itchy, watery eyes
    - 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

age	**dose**
children under 6 years	do not use
children 6 to under 12 years	10 ml every 6 hours
adults and children 12 years and older	20 ml every 6 hours

Other information

- each 10 ml contains: **sodium 10 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 US

PRINCIPAL DISPLAY PANEL - 118 ml Bottle Carton

Children's
Robitussin®
Honey
For Ages 6+

Nighttime
Cough
DM

DEXTROMETHORPHAN HBR
(COUGH SUPPRESSANT)
DOXYLAMINE SUCCINATE (ANTIHISTAMINE)

ALCOHOL
FREE

LONG-ACTING

Relieves:

1. Cough up to 8 hours
2. Runny nose

Taste the
Real Honey

TRUE
SOURCE
CERTIFIED
HONEY ✓

4 FL OZ (118 ml)

CHILDRENS ROBITUSSIN HONEY NIGHTTIME COUGH DM

dextromethorphan hbr, doxylamine succinate solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0031-8762
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg in 10 mL
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg in 10 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: 3WQ0SDW1A)	
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:0031-8762-12	1 in 1 CARTON	05/27/2019	
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 final	part341	05/27/2019	

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

Establishment

Name	Address	ID/FEI	Business Operations
PF Consumer Healthcare Canada ULC		203812479	ANALYSIS(0031-8762) , LABEL(0031-8762) , MANUFACTURE(0031-8762) , PACK(0031-8762)