CHILDRENS ROBITUSSIN HONEY NIGHTTIME COUGH DM- dextromethorphan hbr, doxylamine succinate solution
Haleon US Holdings LLC

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 Drug	M012	05/27/2019	

Labeler - Haleon US Holdings LLC (079944263)

Establishment

Name	Address	ID/FEI	Business Operations
PF Soins de Sante		203812479	ANALYSIS(0031-8762) , LABEL(0031-8762) , MANUFACTURE(0031-8762) , PACK(0031-8762)