ROBITUSSIN DAY AND NIGHT COUGH RELIEF VALUE PACK- dextromethorphan hydrobromide, guaifenesin, chlorpheniramine maleate
Haleon US Holdings LLC

Drug Facts

***Active ingredients (in each 20 mL)*– Children's Robitussin Cough & Chest Congestion DM**

Dextromethorphan HBr 20 mg

Guaifenesin 200 mg

***Purposes*– Children's Robitussin Cough & Chest Congestion DM**

Cough Suppressant

Expectorant

***Uses*– Children's Robitussin Cough & Chest Congestion DM**

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes

***Warnings*– Children's Robitussin Cough & Chest Congestion DM**

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

- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema

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*– Children's Robitussin Cough & Chest Congestion DM**

- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided
- keep dosing cup with product
- mL = milliliter

age	dose
children under 4 years	do not use
children 4 to under 6 years	5 mL every 4 hours
children 6 to under 12 years	10 mL every 4 hours
adults and children 12 years and over	20 mL every 4 hours

***Other information*– Children's Robitussin Cough & Chest Congestion DM**

- **each 20 mL contains:**sodium 21 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

***Inactive ingredients*– Children's Robitussin Cough & Chest Congestion DM**

anhydrous citric acid, carboxymethylcellulose sodium, FD&C blue no. 1, FD&C red no. 40, glycerin, liquid glucose, natural and artificial flavors, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium gluconate, sucralose, xanthan gum

***Questions or comments?*– Children's Robitussin Cough & Chest Congestion DM**

call weekdays from 8 AM to 6 PM EST at **1-800-245-1040**

***Active ingredients (in each 10 mL)*– Children's Robitussin Nighttime Cough Long-Acting DM**

Chlorpheniramine maleate, USP 2 mg

Dextromethorphan HBr, USP 15 mg

***Purposes* –Children's Robitussin Nighttime Cough Long-Acting DM**

Antihistamine

Cough suppressant

***Uses* –Children's Robitussin Nighttime Cough Long-Acting DM**

- 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

***Warnings*– Children's Robitussin Nighttime Cough Long-Acting DM**

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* –Children's Robitussin Nighttime Cough Long-Acting DM**

- 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 over	20 mL every 6 hours

***Other information* –Children's Robitussin Nighttime Cough Long-Acting DM**

- **each 10 mL contains:**sodium 6 mg
- store at 20-25°C (68-77°F)

***Inactive ingredients* –Children's Robitussin Nighttime Cough Long-Acting DM**

anhydrous citric acid, FD&C red no. 40, glycerin, lactic acid, natural and artificial flavors, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose

***Questions or comments?* –Children's Robitussin Nighttime Cough Long-Acting DM**

call weekdays from 8 AM to 6 PM EST at **1-800-245-1040**

Additional Information – Children's Robitussin Day & Night Cough Relief Value Pack

TAMPER-EVIDENT INNER UNITS:

Do Not Use if Tamper-Evident feature on either bottle cap is broken or missing. See individual inner cartons and bottle labels for specific Tamper-Evident features.

Do not take both products within 6 hours of each other.

Children's Robitussin liquid is specially formulated to provide soothing action, control your child's cough – plus relieves other cold symptoms.

PARENTS: Learn about teen medicine abuse

www.StopMedicineAbuse.org

Principal Display Panel – Children's Robitussin Day & Night Cough Relief Value Pack

DAY & NIGHT

COUGH RELIEF

VALUE PACK

Children’s Robitussin

AGES 4 & OVER

Cough & Chest Congestion DM

DEXTROMETHORPHAN HBr

(Cough Suppressant)

GUAIFENESIN

(Expectorant)

Relieves:

- **Chest Congestion/Mucus**
- **Cough**

grapeflavor

4 FL OZ (118 mL)

AGES 6 & OVER

Nighttime Cough Long-Acting DM

CHLORPHENIRAMINE MALEATE

(Antihistamine)

DEXTROMETHORPHAN HBr (Cough Suppressant)

Relieves:

- Cough Up to **8 Hours**
- Runny Nose

Alcohol-free

fruit punchflavor

4 FL OZ (118 mL)

Principal Display Panel – Children's Robitussin Cough & Chest Congestion DM

Children's

Robitussin

FOR AGES 4 & OVER

Cough & Chest Congestion DM

DEXTROMETHORPHAN HBr
(Cough Suppressant)

GUAIFENESIN
(Expectorant)

Relieves:

- Chest Congestion/Mucus
- Cough

BETTER TASTING!*

Great Grape Taste

grapeflavor

4 FL OZ (118 mL)

Children's

Robitussin

FOR AGES 4 & OVER

Cough & Chest Congestion

DM

DEXTROMETHORPHAN HBr
(Cough Suppressant)
GUAIFENESIN (Expectorant)

Relieves:

- ✓ Chest Congestion/Mucus
- ✓ Cough

BETTER TASTING!*
Great Grape Taste

grape flavor

4 FL OZ
(118 mL)

Principal Display Panel – Children’s Robitussin Nighttim e Cough DM

Children’s

Robitussin

AGES 6 & OVER

Nighttime Cough DM

Long-Acting

CHLORPHENIRAMINE MALEATE
(Antihistamine)

DEXTROMETHORPHAN HBr
(Cough Suppressant)

Relieves:

- Cough Up to **8 Hours**
- Runny Nose

Alcohol-Free

fruit punchflavor

4 FL OZ (118 mL)

Children's

Robitussin

AGES 6 & OVER

ROBITUSSIN DAY AND NIGHT COUGH RELIEF VALUE PACK

dextromethorphan hydrobromide, guaifenesin, chlorpheniramine maleate kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0031-2099

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0031-2099-01	1 in 1 CARTON; Type 0: Not a Combination Product	05/12/2020	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BOTTLE	118 mL
Part 2	1 BOTTLE	118 mL

Part 1 of 2

CHILDRENS ROBITUSSIN COUGH AND CHEST CONGESTION DM

dextromethorphan hydrobromide and guaifenesin liquid

Product Information	
Item Code (Source)	NDC:0031-8702
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 20 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
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)	

Product Characteristics

Color	purple	**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-8702-13	1 in 1 CARTON		
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	05/12/2020	

Part 2 of 2

CHILDRENS ROBITUSSIN NIGHTTIME COUGH LONG-ACTING DM

chlorpheniramine maleate, dextromethorphan hydrobromide solution

Product Information

Item Code (Source)	NDC:0031-8692
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg in 10 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	red	**Score**	
Shape		**Size**	
Flavor	FRUIT PUNCH	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-8692-13	1 in 1 CARTON		
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	07/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	05/12/2020	

Labeler - Haleon US Holdings LLC (079944263)