ROBITUSSIN MAXIMUM STRENGTH NIGHTTIME COUGH DM- dextromethorphan hydrobromide, doxylamine succinate solution Haleon US Holdings LLC

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:
 - 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 ifcough 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 14 mg
- store at 20-25°C (68-77°F)

Inactive ingredients

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

Questions or comments?

call weekdays from 9 AM to 5 PM EST at 1-800-245-1040

Additional Information

Do Not Use if foil is missing or broken.

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org

Distributed by: GSK CH, Warren, NJ 07059

For most recent product information,

visit www.robitussin.com

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202881 Front Carton

PRINCIPAL DISPLAY PANEL

ADULT

Robitussin

MAXIMUM STRENGTH

Nighttime Cough DM

DEXTROMETHORPHAN HBr (Cough Suppressant) DOXYLAMINE SUCCINATE (Antihistamine)

- Controls Cough
- Relieves Runny Nose & Sneezing

FAST, EFFECTIVE

cough relief

DM NIGHTTIME MAX

For Ages 12 & Over **4 FL OZ (118 mL)**

ADULT Robitussin



ROBITUSSIN MAXIMUM STRENGTH NIGHTTIME COUGH DM

dextromethorphan hydrobromide, doxylamine succinate solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0031-8718
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: V9BI9B5YI2) (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: K6790BS311)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ 35W2)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TRIACETIN (UNII: XHX3C3X673)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics			
Color	red	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031- 8718-13	1 in 1 CARTON	06/01/2016	
1		118 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
2	NDC:0031- 8718-18	1 in 1 CARTON	06/01/2016	
2		237 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
3	NDC:0031- 8718-24	1 in 1 CARTON	06/01/2016	
3		355 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 Drug	M012	06/01/2016	

Labeler - Haleon US Holdings LLC (079944263)

Revised: 4/2024 Haleon US Holdings LLC