ROBITUSSIN NIGHTTIME COUGH DM SOFT CHEWS- dextromethorphan hydrobromide, doxylamine succinate tablet, chewable
Haleon US Holdings LLC

Drug Facts

Active ingredients (in each chewable tablet)

Dextromethorphan equivalent to dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 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 is chronic such as occurs with smoking, asthma, or chronic bronchitis or emphysema

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers

When using this product

- 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

- do not take more than 4 doses (8 chewable tablets) 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	take 2 chewable tablets every 6 hours, as needed
children under 12 years	do not use

Other information

- **each chewable tablet contains:**potassium 10 mg, sodium 7 mg
- store at a controlled room temperature 20-25°C (68-77°F)

Inactive ingredients

carboxymethylcellulose calcium, carnauba wax, corn syrup solids, crospovidone, D&C red no. 30 aluminum lake, FD&C blue no. 1 aluminum lake, glycerin, mannitol, natural and artificial flavors, pregelatinized starch, simethicone, sodium gluconate, sorbitol, sorbitol solution, sucralose, sucrose, whole dry milk

Questions or comments?

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

Additional Information

Do Not Use if seal under bottle cap imprinted with

“SEALED for YOUR PROTECTION” is broken or missing.

PARENTS:

Learn about teen medicine abuse

www.StopMedicineabuse.org

Distributed by: Haleon, Warren, NJ 07059

Pat. Info www.productpats.com

For most recent product information, visit www.robitussin.com

PRINCIPAL DISPLAY PANEL

NEW! ADULT HALEON

Robitussin

Nighttime Cough DM

Soft CHEWS

DEXTROMETHORPHAN HBr 15 mg
(Cough Suppressant)

DOXYLAMINE SUCCINATE 6.25 mg

(Antihistamine)

FAST relief ANYWHERE

Cough, runny nose & sneezing

UP TO **8HR**COUGH RELIEF

20 CHEWABLE TABLETS

Chew tablets completely before swallowing

Berry flavor

208797 Front Label

ROBITUSSIN NIGHTTIME COUGH DM SOFT CHEWS

dextromethorphan hydrobromide, doxylamine succinate tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0031-9311
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
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOXYMETHYLCELLULOSE CALCIUM (UNII: UTY7PDF93L)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CORN SYRUP (UNII: 9G5L16BK6N)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

GLYCERIN (UNII: PDC6A3C0OX)	
MANNITOL (UNII: 3OWL53L36A)	
STARCH, CORN (UNII: O8232NY3SJ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
SORBITOL (UNII: 506T60A25R)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	
COW MILK (UNII: 917J3173FT)	

Product Characteristics

Color	purple (darker purple speckles)	**Score**	no score
Shape	ROUND	**Size**	21mm
Flavor	BERRY	**Imprint Code**	R
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-9311-20	20 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/19/2024	

Labeler - Haleon US Holdings LLC (079944263)

Revised: 2/2024 Haleon US Holdings LLC