ROBITUSSIN MAXIMUM STRENGTH 12 HOUR COUGH AND MUCUS RELIEF-dextromethorphan hydrobromide, guaifenesin tablet, extended release
Haleon US Holdings LLC

Drug Facts

Active ingredients (in each extended-release tablet)

Dextromethorphan HBr 60 mg

Guaifenesin 1200 mg

Purposes

Cough suppressant

Expectorant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
  - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
  - the intensity of coughing
  - the impulse to cough to help you get to sleep

Warnings

Do not use

- for children under 12 years of age
- 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

- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough accompanied by too much phlegm (mucus)

When using this product

- do not use more than directed

Stop use and ask a doctor if

- cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious illness.

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 (1-800-222-1222).

Directions

- do not crush, chew, or break tablet
- take with a full glass of water
- this product can be administered without regard for timing of meals
- adults and children 12 years and older: 1 tablet every 12 hours; not more than 2 tablets in 24 hours
- children under 12 years of age: do not use

Other information

- **each tablet contains:**magnesium 25 mg
- store between 20-25°C (68-77°F)

Inactive ingredients

carbomer homopolymer type B, copovidone, D&C yellow #10 aluminum lake, hypromellose, magnesium hydroxide, magnesium stearate, microcrystalline cellulose, silicon dioxide

Questions?

call weekdays from 9 AM to 5 PM EST at **1-800-762-4675**

Distributed by: Pfizer, Madison, NJ 07940 USA

Principal Display Panel

NEW!

Robitussin ®

MAXIMUM STRENGTH
12 Hour
Cough & Mucus Relief

EXTENDED-RELEASE TABLETS

GUAIFENESIN & DEXTROMETHORPHAN HYDROBROMIDE
1200 mg/60 mg EXTENDED-RELEASE TABLETS

Expectorant & Cough Suppressant

Actual Size

✓**Controls Cough**

✓**Thins & Loosens Mucus**

8EXTENDED-RELEASE TABLETS

ROBITUSSIN MAXIMUM STRENGTH 12 HOUR COUGH AND MUCUS RELIEF

dextromethorphan hydrobromide, guaifenesin tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0031-8765

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	60 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	1200 mg

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL OR ALLYL SUCROSE CROSSLINKED) (UNII: K6MOM3T5YL)	
COPOVIDONE K25-31 (UNII: D9C330MD8B)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	yellow	**Score**	no score
Shape	OVAL	**Size**	22mm
Flavor		**Imprint Code**	2424
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-8765-04	1 in 1 CARTON	06/14/2019	
1		4 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0031-8765-08	1 in 1 CARTON	06/14/2019	
2		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0031-8765-16	2 in 1 CARTON	06/14/2019	
3		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207602	06/14/2019	

Labeler - Haleon US Holdings LLC (079944263)

Revised: 4/2024 Haleon US Holdings LLC