

**ROBITUSSIN MAXIMUM STRENGTH SEVERE MULTI-SYMPTOM COUGH COLD  
FLU- acetaminophen, dextromethorphan hydrobromide, guaifenesin liquid  
Haleon US Holdings LLC**

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***Drug Facts***

***Active ingredients (in each 20 mL)***

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Guaifenesin 400 mg

***Purposes***

Pain reliever/Fever reducer

Cough suppressant

Expectorant

***Uses***

- temporarily relieves these symptoms occurring with a cold or flu:
  - cough due to minor throat and bronchial irritation
  - minor aches and pains
  - sore throat
  - headache
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive

***Warnings***

**Liver warning:**

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 6 doses in any 24-hour period, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

**Sore throat warning**

If sore throat is severe, persists for more than 2 days, is accompanied or followed by

fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

### **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.
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

### **Ask a doctor before use if you have**

- liver disease
- 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 the blood thinning drug warfarin
- taking any other pain reliever/fever reducer

### **Stop use and ask a doctor if**

- pain or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts.  
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. Prompt medical attention is critical for adults as well as for children, even if you do not notice any signs or symptoms.

### **Directions**

- do not take more than 6 doses in any 24-hour period
- do not exceed recommended dosage. Taking more than the recommended dose (overdose) may cause serious liver damage.
- measure only with dosing cup provided
- keep dosing cup with product
- mL = milliliter
- this adult product is not intended for use in children under 12 years of age

<b>age</b>	<b>dose</b>
adults and children 12 years and over	20 mL every 4 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, edetate disodium, FD&C red no. 40, glycerin, menthol, natural and artificial flavors, polyethylene glycol, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose, triacetin, xanthan gum

### ***Questions or comments?***

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

### **Additional information**

Maximum Strength claim based on maximum levels of active ingredients per 4 hour dose.

ADULT

Robitussin

MAXIMUM STRENGTH

SEVERE MULTI-SYMPTOM

Cough Cold + Flu CF MAX

Do Not Use if breakable ring on bottle cap is separated or missing.

### **PARENTS:**

Learn about teen medicine abuse

**[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)**

Distributed by: Haleon, Warren, NJ 07059

For most recent product information, visit [www.robitussin.com](http://www.robitussin.com)

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### **PRINCIPAL DISPLAY PANEL**

#### **ADULT NEW FORMULA HALEON**

**Robitussin**

MAXIMUM STRENGTH

**SEVERE**

**MULTI-SYMPTOM**

**Cough Cold + Flu**

**ACETAMINOPHEN (Pain Reliever/Fever Reducer)**

**DEXTROMETHORPHAN HBr (Cough Suppressant)  
GUAIFENESIN (Expectorant)**

- ✓Cough, Sore Throat
- ✓Head & Body Aches, Fever
- ✓Chest Congestion
- ✓Thins & Loosens Mucus

**FAST, POWERFUL  
multi-symptom relief**

**CF  
MAX**

For Ages 12 & Over  
8 FL OZ (237 mL)

62000000207716 Front Carton

ADULT

NEW  
FORMULA

HALEON

# Robitussin

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**SEVERE  
MULTI-SYMPTOM**  
Cough Cold + Flu

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# COUGH COLD FLU

acetaminophen, dextromethorphan hydrobromide, guaifenesin liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0031-0100
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYL GALLATE</b> (UNII: 8D4SNN7V92)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

## Product Characteristics

<b>Color</b>	red	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	RASPBERRY, CHOCOLATE, MINT	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-0100-04	1 in 1 CARTON	02/15/2024	

1		118 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
2	NDC:0031-0100-08	1 in 1 CARTON	02/15/2024	
2		237 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	02/15/2024	

**Labeler** - Haleon US Holdings LLC (079944263)

Revised: 1/2024

Haleon US Holdings LLC