#### ROBITUSSIN HONEY SEVERE COUGH, FLU PLUS SORE THROATacetaminophen, dextromethorphan hbr solution Haleon US Holdings LLC

\_\_\_\_\_

#### **Drug Facts**

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

Acetaminophen, USP 650 mg

Dextromethorphan HBr 20 mg

#### Purposes

Pain reliever/Fever reducer

Cough suppressant

#### 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 pain
  - headache
- temporarily reduces fever

#### 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, 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

#### When using this product do not use more than directed.

#### 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

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

#### Other information

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

#### Inactive ingredients

anhydrous citric acid, carboxymethylcellulose sodium, glycerin, natural & artificial flavors, natural grade A honey, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium gluconate, sucralose, xanthan gum, zinc gluconate

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

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

#### Additional information

# Packaged with Tamper-Evident bottle cap. Do Not Use if breakable ring is separated or missing.

#### PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org

Distributed by: Haleon, Warren, NJ 07059

 $\ensuremath{\mathbb{C}}$  2024 Haleon group of companies or its licensor.

Trademarks are owned by or licensed to the Haleon group of companies.

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

Pat. Info <u>www.productpats.com</u>

Made in Canada

#### PRINCIPAL DISPLAY PANEL

Robitussin

Honey

ADULT

# SEVERE

Cough, Flu +

Sore Throat

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

DEXTROMETHORPHAN HBr (Cough Suppressant)

NON-DROWSY

#### **MAXIMUM STRENGTH**

- ✓ Controls Cough
- ✓ Soothes Sore Throat Pain
- ✓ Relieves Fever & Body Aches

Taste the Real Honey with Elderberry

CF

MAX

For Ages 12+

8 FL OZ (237 mL)

6200000207916 - Front Carton

# ADULT

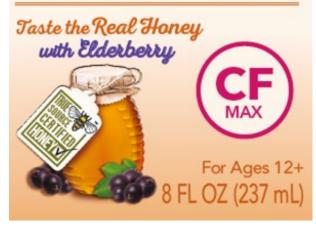
# Robitussin



ACETAMINOPHEN (Pain Reliever/Fever Reducer) DEXTROMETHORPHAN HBr (Cough Suppressant)

## MAXIMUM STRENGTH

- ✓ Controls Cough
- ✓ Soothes Sore Throat Pain
- ✓ Relieves Fever & Body Aches



### **ROBITUSSIN HONEY SEVERE COUGH, FLU PLUS SORE THROAT**

acetaminophen, dextromethorphan hbr solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0031-8771

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg in 20 mL	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL	
Inactive Ingredients			
Ingredient Name		Strength	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS31	1)		
GLYCERIN (UNII: PDC6A3C0OX)			
HONEY (UNII: Y9H1V576FH)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
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)			
ZINC GLUCONATE (UNII: U6WSN5SQ1Z)			

Product Characteristics			
Color	ORANGE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

#### Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0031-8771- 12	1 in 1 CARTON	06/15/2020		
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:0031-8771- 18	1 in 1 CARTON	06/15/2020		
2		237 mL in 1 BOTTLE; Type 0: Not a Combination Product			
Μ	Marketing Information				
	Marketing	Application Number or Monograph	Marketing Start	Marketing End	

Category	Citation	Date	Date
OTC Monograph Drug M0	012	06/15/2020	

# Labeler - Haleon US Holdings LLC (079944263)

Revised: 4/2024

Haleon US Holdings LLC