ROBITUSSIN MAXIMUM STRENGTH SEVERE MULTI-SYMPTOM COUGH COLD FLU NIGHTTIME- acetaminophen, diphenhydramine hcl liquid
Haleon US Holdings LLC

Drug Facts

Active ingredients (in each 20 mL)

Acetaminophen 650 mg

Diphenhydramine HCl 25 mg

Purposes

Pain reliever/Fever reducer

Antihistamine/Cough suppressant

Uses

- temporarily relieves these symptoms occurring with a cold or flu, hay fever, or other respiratory allergies:
  - cough due to minor throat and bronchial irritation
  - headache
  - sore throat
  - minor aches and pains
  - runny nose
  - sneezing
  - itchy, watery eyes
  - itching of the nose or throat
- temporarily relieves your cough to help you rest
- 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

- to sedate a child or to make a child sleepy
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- with any other drug containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- liver disease
- trouble urinating due to an enlarged prostate gland
- glaucoma
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking any other pain reliever/fever reducer
- 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 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 12 years and over	20 mL every 4 hours
children under 12 years	do not use

Other information

- **each 20 mL contains:**sodium 12 mg
- store at 20-25°C (68-77°F)

Inactive ingredients

anhydrous citric acid, artificial flavor, edetate disodium, FD&C red no. 40, glycerin, menthol, polyethylene glycol, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose

Questions or comments?

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

Additional information

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

ADULT

Robitussin

MAXIMUM STRENGTH

SEVERE MULTI-SYMPTOM

Cough Cold + Flu **CF**NIGHTTIME MAX

Distributed by: Haleon, Warren, NJ 07059

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

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PRINCIPAL DISPLAY PANEL

ADULT NEW FORMULA HALEON

Robitussin

MAXIMUM STRENGTH

SEVERE
MULTI-SYMPTOM
Cough Cold + Flu

Nighttime

ACETAMINOPHEN (Pain Reliever/Fever Reducer)
DIPHENHYDRAMINE HCl (Antihistamine/Cough Suppressant)

Relieves Cough to Help You Rest

✓Cough, Sore Throat
✓Head & Body Aches, Fever
✓Runny Nose, Sneezing

FAST, POWERFUL
multi-symptom relief

CF
NIGHTTIME
MAX

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

207723 Front Carton

ROBITUSSIN MAXIMUM STRENGTH SEVERE MULTI-SYMPTOM COUGH COLD FLU NIGHTTIME

acetaminophen, diphenhydramine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0031-0101
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20 mL
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	red	**Score**	
Shape		**Size**	
Flavor	CHERRY, RASPBERRY,	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-0101-04	1 in 1 CARTON	02/15/2024	
1		118 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)