ROBITUSSIN SEVERE MULTI-SYMPTOM COUGH COLD FLU NIGHTTIME- acetaminophen, diphenhydramine hydrochloride, phenylephrine hydrochloride solution
Haleon US Holdings LLC

Drug Facts

Active ingredients (in each 20 mL)

Acetaminophen, USP 650 mg

Diphenhydramine HCl, USP 25 mg

Phenylephrine HCl, USP 10 mg

Purposes

Pain reliever/Fever reducer

Antihistamine/Cough suppressant

Nasal decongestant

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
  - nasal congestion
  - headache
  - sore throat
  - minor aches and pains
  - runny nose
  - sneezing
  - itchy, watery eyes
  - itching of the nose and throat
- 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
- 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.
- with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have
- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- 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 oral nasal decongestant or stimulant
- taking any other pain reliever/fever reducer
- taking sedatives or tranquilizers

When using this product
- **do not use more than directed**
- 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
- you get nervous, dizzy, or sleepless
- pain, cough, or nasal congestion 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 9 AM to 5 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.

Distributed by: GSK Consumer Healthcare, Warren, NJ 07059

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

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Made in Canada

Principal Display Panel

ADULT

Robitussin

MAXIMUM STRENGTH

SEVERE

Multi-Symptom

Cough Cold + Flu

Nighttime

ACETAMINOPHEN (Pain Reliever/Fever Reducer)

DIPHENHYDRAMINE HCl (Antihistamine/Cough Suppressant)

PHENYLEPHRINE HCl (Nasal Decongestant)

Cough, Sore Throat

Body Aches, Fever

Nasal Congestion

Runny Nose

POWERFUL

Multi-symptom relief

CF NIGHTTIME MAX

For Ages 12 & Over

4 FL OZ (118 mL)

62000000077079 Front Carton

ROBITUSSIN SEVERE MULTI-SYMPTOM COUGH COLD FLU NIGHTTIME

acetaminophen, diphenhydramine hydrochloride, phenylephrine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0031-8752
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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 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:0031-8752-12	1 in 1 CARTON	07/01/2015	
1		118 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
2	NDC:0031-8752-18	1 in 1 CARTON	07/01/2015	
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	M0012	07/01/2015	

Labeler - Haleon US Holdings LLC (079944263)

Revised: 4/2024 Haleon US Holdings LLC