ROBITUSSIN HONEY SEVERE COUGH, FLU PLUS SORE THROAT NIGHTTIME- acetaminophen and diphenhydramine hydrochloride solution
Haleon US Holdings LLC

Drug Facts

Active ingredients (in each 20 mL)

Acetaminophen 650 mg

Diphenhydramine HCl 25 mg

Purpose

Pain reliever/Fever reducer

Antihistamine/Cough suppressant

Uses

- temporarily relieves these symptoms occurring with a cold or flu, hay fever, or other upper respiratory allergies:
    - cough due to minor throat and bronchial irritation
    - minor aches and pains
    - sore throat pain
    - headache
    - runny nose, sneezing, itchy watery eyes
    - itching of the nose and throat
- temporarily relieves your cough to help you sleep
- 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 product containing diphenhydramine, even one used on skin

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, emphysema or chronic bronchitis
- if you have glaucoma or difficulty in urination due to enlargement of prostate gland

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin
- taking any other pain reliever/fever reducer

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

- 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 22 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

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.

Distributed by: Haleon, Warren, NJ 07059

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

Pat. Info www.productpats.com

Made in Canada

PRINCIPAL DISPLAY PANEL

ADULT
Robitussin

Honey

Nighttime

SEVERE
Cough, Flu +
Sore Throat

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

MAXIMUM STRENGTH

- ✓ Controls Cough
- ✓ Relieves Runny Nose & Sneezing
- ✓ Relieves Fever & Body Aches

Taste the Real Honey
with Vanilla

CF
NIGHTTIME
MAX

For Ages 12+

8 FL OZ (237 mL)

ROBITUSSIN HONEY SEVERE COUGH, FLU PLUS SORE THROAT NIGHTTIME

acetaminophen and diphenhydramine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0031-8770

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)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
HONEY (UNII: Y9H1V576FH)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
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)	

Product Characteristics

Color	ORANGE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-8770-12	1 in 1 CARTON	06/15/2020	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0031-8770-18	1 in 1 CARTON	06/15/2020	
2		237 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC Monograph Drug	M012	06/15/2020	

Labeler - Haleon US Holdings LLC (079944263)

Revised: 4/2024 Haleon US Holdings LLC