**ROBITUSSIN MAXIMUM STRENGTH SEVERE MULTI-SYMPTOM 7 IN 1 RELIEF NIGHTTIME- acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate capsule, liquid filled**
**Haleon US Holdings LLC**

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## *Drug Facts*

### *Active ingredients (in each liquid-filled capsule)*

Acetaminophen, USP 325 mg

Dextromethorphan HBr, USP 15 mg

Doxylamine Succinate, USP 6.25 mg

### *Purposes*

Pain reliever/Fever reducer

Cough suppressant

Antihistamine

### *Uses*

- temporarily relieves these symptoms occurring with a cold or flu, hay fever, or other upper respiratory allergies:
  - headache
  - sore throat
  - cough
  - minor aches and pains
  - runny nose
  - sneezing
  - itchy, watery eyes
  - itching of the nose or throat
- temporarily reduces fever

### *Warnings*

#### Liver warning

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

- more than 8 capsules 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.

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

- liver disease
- glaucoma
- trouble urinating due to an enlarged prostate gland
- 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
- 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
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.
- new symptoms occur

**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 8 capsules in any 24-hour period
- do not exceed recommended dosage. Taking more than the recommended dose (overdose) may cause serious liver damage.
- this adult product is not intended for use in children under 12 years of age

| **age** | **dose** |
|---|---|
| adults and children 12 years and over | 2 capsules every 6 hours |
| children under 12 years | do not use |

***Other information***

- store at 20-25°C (68-77°F). Avoid excessive heat above 40°C (104°F).

***Inactive ingredients***

D&C yellow no. 10, FD&C blue no. 1, gelatin, glycerin, mineral oil, pharmaceutical ink, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution

***Questions or comments?***

Call weekdays from 9 AM to 5 PM EST at **1 800-762-4675**

Distributed by: Pfizer, Madison, NJ 07940 USA

**PRINCIPAL DISPLAY PANEL**

ADULT

**Robitussin ®**

- **MAXIMUM STRENGTH**
- **SEVERE**
  Multi-Symptom
  7 in 1 Relief

**ACETAMINOPHEN (Pain Reliever/Fever Reducer)**
DEXTROMETHORPHAN HBr (Cough Suppressant)
DOXYLAMINE SUCCINATE (Antihistamine)

**CF**
**NIGHTTIME**
**MAX**

1. Cough, Sore Throat
2. Body Aches, Fever
3. Runny Nose, Sneezing
4. Itchy Throat

For Ages 12 & Over

**10**
LIQUID-FILLED

CAPSULES



# ROBITUSSIN MAXIMUM STRENGTH SEVERE MULTI-SYMPTOM 7 IN 1 RELIEF NIGHTTIME

acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate capsule, liquid filled

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:0031-8744 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **ACETAMINOPHEN** (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 325 mg |
| **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 15 mg |
| **DOXYLAMINE SUCCINATE** (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL) | DOXYLAMINE SUCCINATE | 6.25 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **D&C YELLOW NO. 10** (UNII: 35SW5USQ3G) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **GELATIN, UNSPECIFIED** (UNII: 2G86QN327L) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **MINERAL OIL** (UNII: T5L8T28FGP) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **POVIDONE, UNSPECIFIED** (UNII: FZ989GH94E) | |

| | |
|---|---|
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SORBITOL** (UNII: 506T60A25R) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | green | **Score** | no score |
| **Shape** | OVAL | **Size** | 16mm |
| **Flavor** | | **Imprint Code** | R |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0031-8744-10 | 5 in 1 CARTON | 07/01/2018 | |
| **1** | | 2 in 1 BLISTER PACK; 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 | 07/01/2015 | |

## Labeler - Haleon US Holdings LLC (079944263)

Revised: 4/2024 Haleon US Holdings LLC