

**ROBITUSSIN DIRECT SORE THROAT PAIN- acetaminophen tablet, coated**  
**Haleon US Holdings LLC**

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***Drug Facts***

***Active ingredient (in each caplet)***

Acetaminophen 500 mg

***Purposes***

Pain reliever/Fever reducer

***Uses***

- temporarily relieves minor aches and pains due to:
- sore throat
- headache
- backache
- toothache
- premenstrual and menstrual cramps
- the common cold
- minor pain of arthritis
- muscular aches
- temporarily reduces fever

***Warnings***

**Liver warning:**

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

- more than 4,000 mg of acetaminophen in 24 hours
- 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**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are allergic to acetaminophen or any of the inactive ingredients in this product

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

**Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin**

**Stop use and ask a doctor if**

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- 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 directed**
- adults and children 12 years of age and over: take 1 caplet every 4 hours, or 2 caplets every 6 hours, while symptoms last
- do not take more than 6 caplets in any 24 hours, unless directed by a doctor
- do not take for more than 10 days unless directed by a doctor
- children under 12 years of age: ask a doctor

***Other information***

- store at 25°C (77°F)

***Inactive ingredients***

castor oil, hypromellose, povidone, pregelatinized starch, sodium starch glycolate, stearic acid

**Questions? call weekdays from 9 AM to 5 PM EST at 1-800-245-1040**

**Additional Information**

**Do not use if safety seal under cap printed with “Sealed for Your Protection” is broken or missing.**

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**Lift Here for More Drug Facts**

**PRINCIPAL DISPLAY PANEL**

**NEW**

**Robitussin**

**Sore Throat Pain**

**Acetaminophen  
(Pain Reliever, Fever Reducer)**

**direct**

**18 Caplets**

Actual size

L-0630-175-44-UPC\_ORG - Front Label



**ROBITUSSIN DIRECT SORE THROAT PAIN**

acetaminophen tablet, coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0031-9301
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>CASTOR OIL</b> (UNII: D5340Y2I9G)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	44;175
<b>Contains</b>			

### Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0031-9301-01	18 in 1 BOTTLE; Type 0: Not a Combination Product	07/15/2022	

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M012	07/15/2022	

**Labeler** - Haleon US Holdings LLC (079944263)