

**ROBITUSSIN HONEY SEVERE COUGH, FLU PLUS SORE THROAT-  
acetaminophen, dextromethorphan hbr solution  
GlaxoSmithKline Consumer Healthcare Holdings (US) LLC**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

-----  
**Drug Facts**

**Active ingredients (in each 20 ml)**

Acetaminophen, USP 650 mg

Dextromethorphan HBr, USP 20 mg

**Purposes**

Pain reliever/Fever reducer

Cough suppressant

**Uses**

- temporarily relieves these symptoms occurring with a cold or flu:
  - o cough due to minor throat and bronchial irritation
  - o minor aches and pains
  - o sore throat pain
  - o headache
- 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**

- 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
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, 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

### **When using this product do not use more than directed.**

### **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

<b>age</b>	<b>dose</b>
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 21 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, zinc gluconate

**Questions or comments?**

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

Distributed by: Pfizer, Madison, NJ 07940 USA

©2020 Pfizer Inc.

For most recent product information, visit [www.robitussin.com](http://www.robitussin.com)

For US Patent or Application status use [www.productpats.com](http://www.productpats.com)

**Should be 18 or older to purchase**

**PARENTS:**

Learn about teen medicine abuse

[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

**PRINCIPAL DISPLAY PANEL**

NDC 0031 8771 18

**Robitussin®**

**Honey**

ADULT  
NEW!

SEVERE  
Cough, Flu +  
Sore Throat

**ACETAMINOPHEN (Pain Reliever/Fever Reducer)**

DEXTROMETHORPHAN HBr (Cough Suppressant)

NON-DROWSY

**MAXIMUM STRENGTH**

1. Controls Cough
2. Soothes Sore Throat Pain
3. Relieves Fever & Body Aches

Taste the Real Honey  
with Elderberry

**CF**  
MAX

For Ages 12+

8 FL OZ (237 ml)



## ROBITUSSIN HONEY SEVERE COUGH, FLU PLUS SORE THROAT

acetaminophen, dextromethorphan hbr solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0031-8771
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH)	DEXTROMETHORPHAN	20 mg

(DEXTROMETHORPHAN - UNII:7355X3ROTS)

HYDROBROMIDE

in 20 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HONEY</b> (UNII: Y9H1V576FH)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	
<b>SODIUM GLUCONATE</b> (UNII: R6Q3791S76)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>ZINC GLUCONATE</b> (UNII: U6WSN5SQ1Z)	

**Product Characteristics**

<b>Color</b>	ORANGE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-8771-12	1 in 1 CARTON	06/15/2020	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0031-8771-18	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 final	part341	06/15/2020	

**Labeler** - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)