ROBITUSSIN MAXIMUM STRENGTH SEVERE COUGH PLUS SORE THROAT- acetaminophen, dextromethorphan hydrobromide liquid
Richmond Division of Wyeth

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.

Robitussin® Maximum Strength Severe Cough Plus Sore Throat

Drug Facts

Active ingredients (in each 20 ml)	***Purposes***
Acetaminophen, USP 650 mg	Pain reliever/Fever reducer
Dextromethorphan HBr, USP 20 mg	Cough suppressant

Uses

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

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 13 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

anhydrous citric acid, FD&C red no. 40, glycerin, menthol, natural & artificial flavor, polyethylene glycol, polysorbate 80, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose, xanthan gum

Questions or comments?

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

Made in Canada

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

Distributed by: Pfizer, Madison, NJ 07940 USA

PRINCIPAL DISPLAY PANEL - 118 ml Bottle Label

ADULT
Robitussin®

MAXIMUM STRENGTH

SEVERE
Cough +
Sore Throat

CF
MAX

ACETAMINOPHEN (Pain Reliever/Fever Reducer)
DEXTROMETHORPHAN HBr (Cough Suppressant)

Strong Cooling Liquid
Non-Drowsy

4 FL OZ (118 ml)

PRINCIPAL DISPLAY PANEL - 118 ml Bottle Carton

ADULT

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MAXIMUM STRENGTH

SEVERE
Cough +
Sore Throat

ACETAMINOPHEN (Pain Reliever/Fever Reducer)

DEXTROMETHORPHAN HBr (Cough Suppressant)

Relieves:

- Cough
- Sore Throat Pain

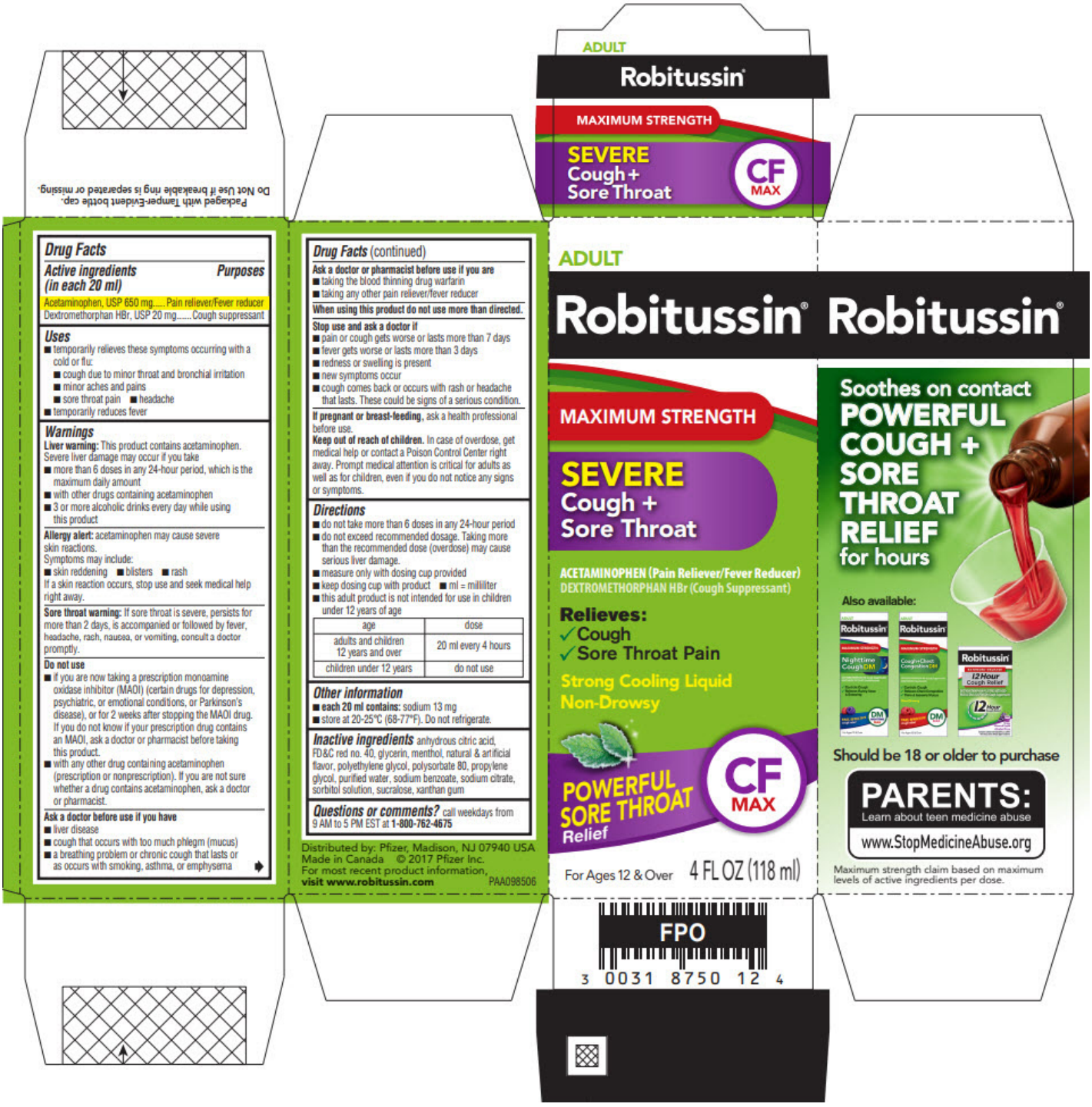
Strong Cooling Liquid
Non-Drowsy

POWERFUL
SORE THROAT
Relief

CF
MAX

For Ages 12 & Over

4 FL OZ (118 ml)



ROBITUSSIN MAXIMUM STRENGTH SEVERE COUGH PLUS SORE THROAT

acetaminophen, dextromethorphan hydrobromide liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0031-8750
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
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	RED	**Score**	
Shape		**Size**	
Flavor	MINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-8750-12	1 in 1 CARTON	04/10/2017	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0031-8750-18	1 in 1 CARTON	04/10/2017	
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	04/10/2017	

Labeler - Richmond Division of Wyeth (829390835)

Establishment

Name	Address	ID/FEI	Business Operations
PF Consumer Healthcare Canada ULC		203812479	ANALYSIS(0031-8750) , LABEL(0031-8750) , MANUFACTURE(0031-8750) , PACK(0031-8750)