

ROBITUSSIN SEVERE MULTI-SYMPATOM COUGH COLD FLU- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride 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® Severe Multi-Symptom Cough Cold Flu

Drug Facts

Active ingredients (in each 20 ml)	Purposes
Acetaminophen, USP 650 mg	Pain reliever/Fever reducer
Dextromethorphan HBr, USP 20 mg	Cough suppressant
Guaifenesin, USP 400 mg	Expectorant
Phenylephrine HCl, USP 10 mg	Nasal decongestant

Uses

- temporarily relieves these symptoms occurring with a cold or flu:
 - cough due to minor throat and bronchial irritation
 - nasal congestion
 - sinus congestion and pressure
 - minor aches and pains
 - sore throat
 - headache
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive

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
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- 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 oral nasal decongestant or stimulant
- taking any other pain reliever/fever reducer

When using this product do not use more than directed

Stop use and ask a doctor if

- you get nervous, dizzy, or sleepless
- pain, cough, or nasal congestion 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 14 mg

- store at 20-25°C (68-77°F)

Inactive ingredients

anhydrous citric acid, edetate disodium, FD&C red no. 40, glycerin, menthol, natural and artificial flavors, polyethylene glycol, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose, triacetin, 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.robittussin.com**

Distributed by: Pfizer, Madison, NJ 07940 USA

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label

ADULT

Robitussin®

MAXIMUM STRENGTH

SEVERE

**Multi-Symptom
Cough Cold + Flu**

CF

MAX

**ACETAMINOPHEN (Pain Reliever/Fever Reducer)
DEXTROMETHORPHAN HBr (Cough Suppressant)
GUAIFENESIN (Expectorant)
PHENYLEPHRINE HCl (Nasal Decongestant)**

4 FL OZ (118 ml)

Do Not Use if breakable ring on bottle cap is separated or missing.

Active ingredients (in each 20 ml): Acetaminophen, USP 650 mg; Dextromethorphan HBr, USP 20 mg; Guaifenesin, USP 400 mg; Phenylephrine HCl, USP 10 mg

Uses: temporarily relieves these symptoms occurring with a cold or flu: cough due to minor throat and bronchial irritation; nasal congestion; sinus congestion and pressure; minor aches and pains; sore throat; headache; temporarily reduces fever; helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive.

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; heart disease; high blood pressure; thyroid disease; diabetes; 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 oral nasal decongestant or stimulant; taking any other pain reliever/fever reducer.

ADULT

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MAXIMUM STRENGTH

**SEVERE
Multi-Symptom
Cough Cold + Flu**

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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. 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 14 mg. Store at 20-25°C (68-77°F).

Inactive ingredients: anhydrous citric acid, edetate disodium, FD&C red no. 40, glycerin, menthol, natural & artificial flavors, polyethylene glycol, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose, triacetin, xanthan gum

Questions or comments? call weekdays from 9 AM to 5 PM EST at 1-800-762-4675

Distributed by:
Pfizer, Madison, NJ 07940 USA **LOT:**
© 2015 Pfizer Inc. Made in Canada
For most recent product information, visit www.robittussin.com **EXP:**

PAA056713

PRINCIPAL DISPLAY PANEL - 118 ml Bottle Carton

ADULT

Robitussin®

MAXIMUM STRENGTH

SEVERE

Multi-Symptom

Cough Cold + Flu

ACETAMINOPHEN (Pain Reliever/Fever Reducer)

DEXTROMETHORPHAN HBr (Cough Suppressant)

GUAIFENESIN (Expectorant)

PHENYLEPHRINE HCl (Nasal Decongestant)

☐ Cough, Sore Throat

☐ Body Aches, Fever

☐ Nasal Congestion

☐ Chest Congestion

Non-Drowsy

POWERFUL

multi-symptom relief

CF

MAX

For Ages 12 & Over

4 FL OZ (118 ml)

ADULT

Robitussin

MAXIMUM STRENGTH

SEVERE
Multi-Symptom
Cough Cold + Flu



ADULT

Robitussin® Robitussin®

MAXIMUM STRENGTH

SEVERE
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ACETAMINOPHEN (Pain Reliever/Fever Reducer)
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PHENYLEPHRINE HCl (Nasal Decongestant)

- ✓ Cough, Sore Throat
- ✓ Body Aches, Fever
- ✓ Nasal Congestion
- ✓ Chest Congestion

Non-Drowsy



POWERFUL
multi-symptom relief



STRONG SOOTHING ACTION

and powerful relief for your worst symptoms



Also available:



Should be 18 or older to purchase

PARENTS:

Learn about teen medicine abuse

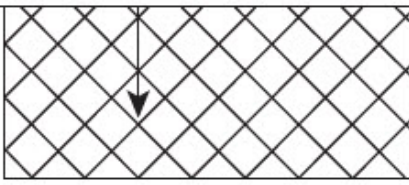
www.StopMedicineAbuse.org

Distributed by: Pfizer, Madison, NJ 07940 USA © 2017 Pfizer Inc.
Made in Canada

For Ages 12 & Over 4 FL OZ (110 mL)

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

PAA097786



Do Not Use if breakable ring is separated or missing.
Packaged with Tamper-Evident bottle cap.

Drug Facts

Active ingredients (in each 20 ml) Purposes

Acetaminophen, USP 650 mg.....	Pain reliever/Fever reducer
Dextromethorphan HBr, USP 20 mg	Cough suppressant
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Uses

- temporarily relieves these symptoms occurring with a cold or flu:
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Drug Facts (continued)

- 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 oral nasal decongestant or stimulant
- taking any other pain reliever/fever reducer

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Stop use and ask a doctor if

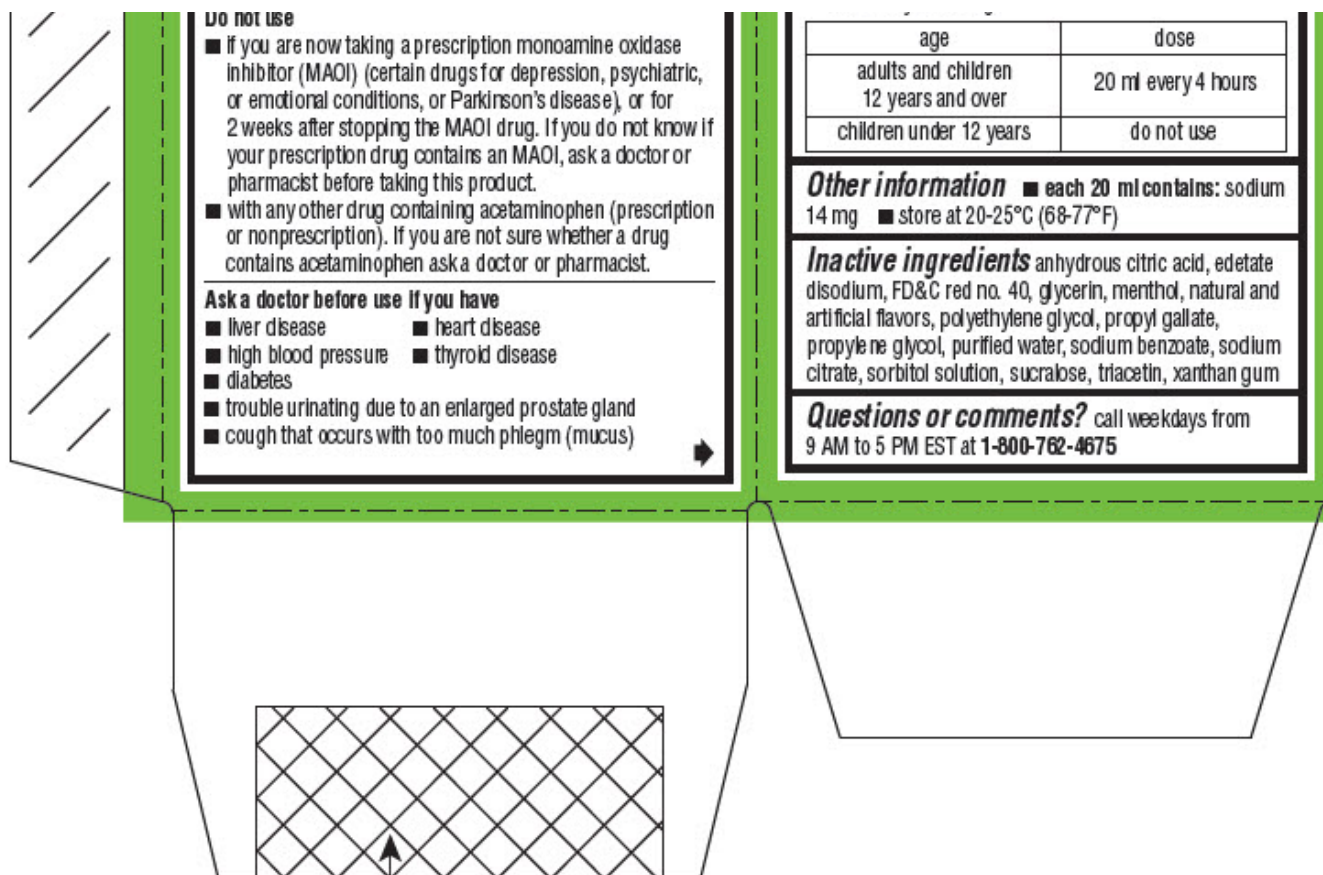
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ROBITUSSIN SEVERE MULTI-SYMPTOM COUGH COLD FLU

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0031-8751
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
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	

MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TRIACETIN (UNII: XHX3C3X673)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor	RASPBERRY, CHOCOLATE, MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-8751-12	1 in 1 CARTON	05/01/2015	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0031-8751-18	1 in 1 CARTON	05/01/2015	
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	05/01/2015	

Labeler - Richmond Division of Wyeth (829390835)

Establishment

Name	Address	ID/FEI	Business Operations
PF Consumer Healthcare Canada ULC		203812479	ANALYSIS(0031-8751) , LABEL(0031-8751) , MANUFACTURE(0031-8751) , PACK(0031-8751)