ROBITUSSIN LONG-ACTING COUGHGELS- dextromethorphan hydrobromide capsule, liquid filled
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® LONG-ACTING COUGHGELS®

Drug Facts

Active ingredient (in each liquid-filled capsule)

Dextromethorphan HBr, USP 15 mg

Purpose

Cough suppressant

Use

temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold.

Warnings

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.

Ask a doctor before use if you have

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

Stop use and ask a doctor if cough lasts for more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. 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.

Directions

- do not take more than 8 capsules in any 24-hour period
- this adult product is not intended for use in children under 12 years of age

age	dose
adults and children 12 years and over	take 2 capsules every 6 to 8 hours, as needed
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)
- protect from light

Inactive ingredients

FD&C blue no. 1, FD&C red no. 40, fractionated coconut oil, gelatin, glycerin, mannitol, pharmaceutical ink, polyethylene glycol, povidone, propyl gallate, propylene glycol, purified water, sorbitol, sorbitol anhydrides

Questions or comments?

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

Distributed by: Pfizer, Madison, NJ 07940 USA

PRINCIPAL DISPLAY PANEL - 20 Capsule Bottle Label

ADULT

Robitussin®

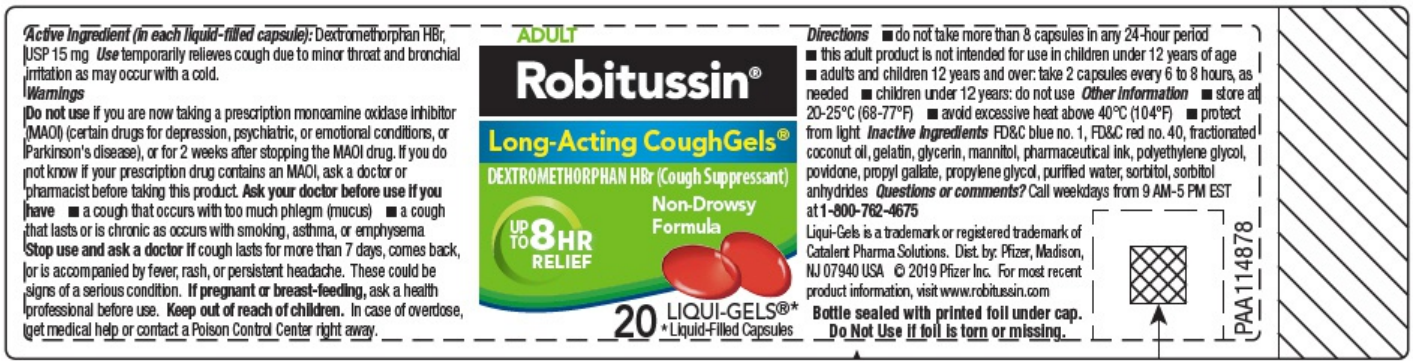
Long-Acting CoughGels®

DEXTROMETHORPHAN HBr (Cough Suppressant)

Non-Drowsy
Formula

UP
TO
8 HR
RELIEF

20
LIQUI-GELS®*
*Liquid-Filled Capsules



PRINCIPAL DISPLAY PANEL - 20 Capsule Bottle Carton

ADULT
NEW LOOK!

Robitussin®

Long-Acting
CoughGels®

DEXTROMETHORPHAN HBr
(Cough Suppressant)

UP
TO
8 HR

RELIEF

Non-Drowsy
Formula

For Ages 12 & Over

20
LIQUI-GELS®*
*LIQUID FILLED CAPSULES

ADULT

Robitussin®

Long-Acting CoughGels®

UP TO 8HR RELIEF

ADULT

NEW LOOK!

Robitussin®

Long-Acting CoughGels®

DEXTROMETHORPHAN HBr (Cough Suppressant)

UP TO 8HR RELIEF

Non-Drowsy Formula

20

LIQUI-GELS®*

*LIQUID FILLED CAPSULES

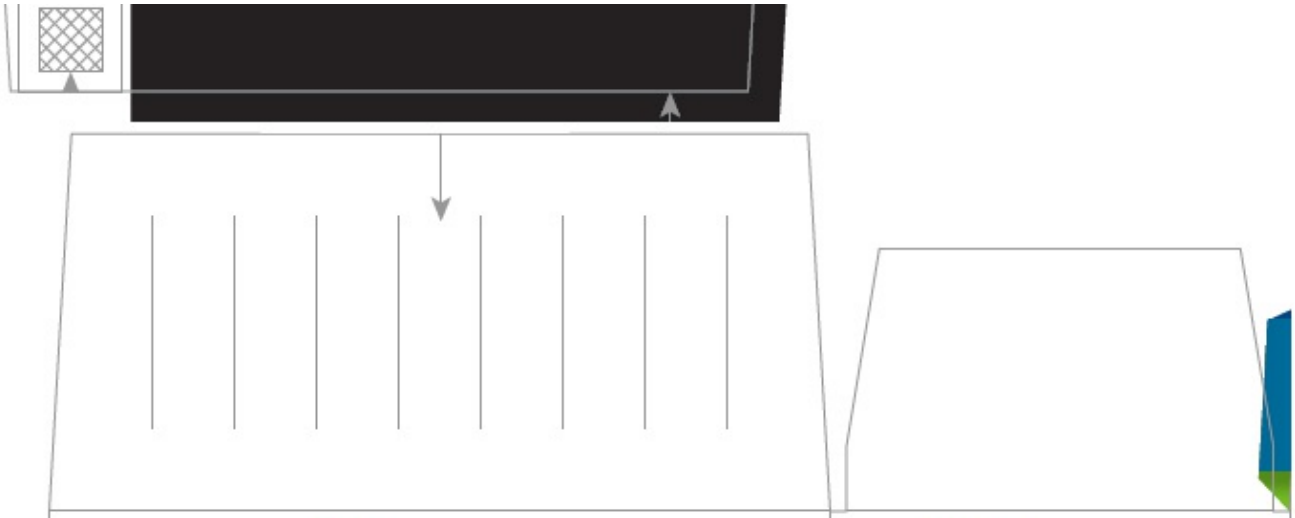
For Ages 12 & Over

ADULT

Robitussin®

1 BOTTLE INSIDE

ACTUAL SIZE



ADULT

Robitussin®

Long-Acting CoughGels®

Drug Facts

Active ingredient (in each liquid-filled capsule) — **Purpose**

Dextromethorphan HBr, USP 15 mg ..... Cough suppressant

Use temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold.

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Drug Facts (continued)

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ADULT

Robitussin®

Long-Acting CoughGels®

Should be 18 or older to purchase

PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

Bottle sealed with printed foil under cap.
Do Not Use if foil is torn or missing.

Distributed by: Pfizer, Madison, NJ 07940 USA

Made in India
For most recent product information, visit www.robitussin.com

100% For Position Only
3 0031 8743 20 1

PAA114880

ROBITUSSIN LONG-ACTING COUGHGELS

dextromethorphan hydrobromide capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0031-8743
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg

Inactive Ingredients	
Ingredient Name	**Strength**
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
COCONUT OIL (UNII: Q9L0O73W7L)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
MANNITOL (UNII: 3OWL53L36A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color	RED	**Score**	no score
Shape	OVAL	**Size**	10mm
Flavor		**Imprint Code**	R
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0031-8743-20	1 in 1 CARTON	01/04/2019	
1		20 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	01/04/2019	

Labeler - Richmond Division of Wyeth (829390835)

Establishment

Name	Address	ID/FEI	Business Operations
PF Consumer Healthcare Canada ULC		203812479	ANALYSIS(0031-8743) , LABEL(0031-8743) , PACK(0031-8743)

Revised: 2/2019 Richmond Division of Wyeth