ROBITUSSIN LINGERING COLD LONG-ACTING COUGHGELS- dextromethorphan hbr 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 Lingering Cold Long-Acting CoughGels
(dextromethorphan HBr)

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 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**

PRODUCT PACKAGING

The product packaging shown below represents a sample of that currently in use. Additional packaging may also be available.

ADULT

Robitussin LINGERING COLD Long-Acting CoughGels

DEXTROMETHORPHAN HBr (Cough Suppressant)

Relieves: Cough for up to **8 Hours**

Non-Narcotic Formula

Non-Drowsy

For Ages 12 & Over

20 LIQUI-GELS*

*Liquid-Filled Capsules

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

Stop use and ask a doctor if cough lasts more than 7 days.

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

ADULT

Robitussin®

LINGERING COLD

Long-Acting CoughGels®

DEXTROMETHORPHAN HBr (Cough Suppressant)

Relieves:
Cough
for up to
8 Hours

Non-Narcotic

Dextromethorphan HBr,
USP 15 mg .....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.

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24-hour period

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For most recent product information, visit www.robitussin.com
LIQUI-GELS® is a trademark or registered trademark of Catalent Pharma Solutions.

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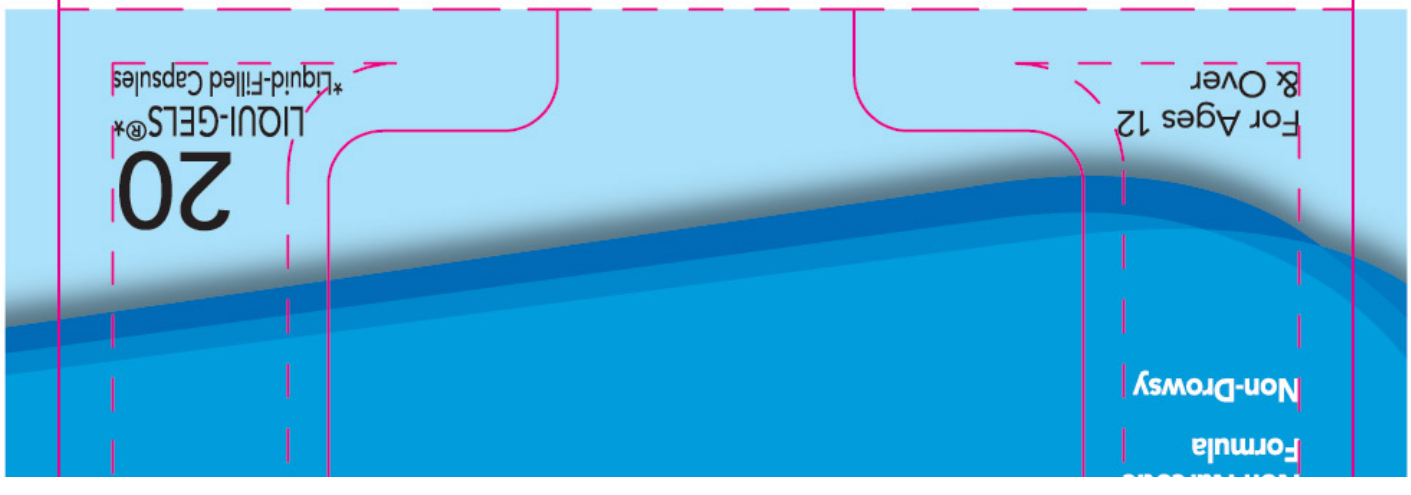

ROBITUSSIN LINGERING COLD LONG-ACTING COUGHGELS

dextromethorphan hbr capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0031-8741
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 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 (clear red)	**Score**	no score
Shape	OVAL (oval softgel)	**Size**	10mm
Flavor		**Imprint Code**	R
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-8741-20	1 in 1 BLISTER PACK	06/06/2011	
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	06/06/2011	

Labeler - Richmond Division of Wyeth (829390835)

Establishment

Name	Address	ID/FEI	Business Operations
PF Consumer Healthcare Canada ULC		203812479	ANALYSIS(0031-8741) , LABEL(0031-8741) , PACK(0031-8741)

Revised: 12/2018 Richmond Division of Wyeth