

**DEXTROMETHORPHAN HYDROBROMIDE- dextromethorphan hydrobromide capsule,
liquid filled**

J.P. BUSINESS ENTERPRISE

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.

DEXTROMETHORPHAN HBr 15mg SOFT GELATIN CAPSULES

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
- trouble urinating due to an enlarged prostate gland

Stop use and ask 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

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, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan, titanium dioxide

Questions or comments?

1-888-333-9792

Distributed By: J.P Business Enterprise
Lake Grove, NY 11755

PRINCIPAL DISPLAY PANEL - 15 Softgel Bottle Carton**VALUMEDS**

Compare to the Active Ingredient of
ROBITUSSIN[®] LONG-ACTING COUGHGELS^{®*}

**ADULT LONG-LASTING
COUGH RELIEF**

FOR AGES
12 & Over

DEXTROMETHORPHAN HBr, USP 15 mg

COUGH SUPPRESSANT

- Relieves cough for up to 8 hours
- Non- Drowsy
- Non-Narcotic Formula

15 SOFTGELS**

**Liquid Filled Capsules

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KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

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LOT:
EXP:

0 402332 04628 5

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

ORIG 8/13

This product is not manufactured or distributed by Pfizer, Inc., owner of the registered trademark Robitussin® Lingerin Cold Long-Acting CoughGels®

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Lake Grove, NY 11755

DEXTROMETHORPHAN HYDROBROMIDE
dextromethorphan hydrobromide capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59105-006
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
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE K30 (UNII: U725QWY32X)	
WATER (UNII: 059QF0KO0R)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red	Score	no score
Shape	OVAL	Size	13mm
Flavor		Imprint Code	404
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59105-006-15	1 in 1 CARTON	12/01/2014	
1		15 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	12/01/2014	

Labeler - J.P. BUSINESS ENTERPRISE (078775890)**Establishment**

Name	Address	ID/FEI	Business Operations
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MEDGEL PVT LTD		677385498	manufacture(59 105-006)
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Revised: 12/2019

J.P. BUSINESS ENTERPRISE