

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

Spirit Pharmaceuticals LLC

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.

VALUMEDS™ ADULT LONG-LASTING COUGH RELIEF

Drug Facts

Active ingredient (in each softgel)

Dextromethorphan HBr, USP 15mg

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 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 softgels 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 red no. 40, gelatin, glycerin, polyethylene glycol 400, propylene glycol, povidone, sorbitol sorbitan, titanium dioxide

Questions or comments?

1-888-333-9792

PRINCIPAL DISPLAY PANEL

Compare to the Active Ingredient of
ROBITUSSIN® LONG ACTING COUGH GELS ©*

VALUMEDS™

ADULT LONG-LASTING
Cough Relief FOR AGES 12 & OVER

Dextromethorphan HBr, 15 mg

Cough suppressant

Relieves cough for up to 8 hours

EXP: _____
 LOT: _____
 0 40232 6054 1 3
 186-0915
 TAMERS 2 VERT: 2 ON OR USE IF PRINTED SURETY
 SEAL AND 50 CAPS IN OVEN OR MASHING

ValuMed
 ADULT LONG-LASTING
COUGH RELIEF
 DEXTROMETHORPHAN HBr 15 mg
 COUGH SUPPRESSANT
 Relieves cough for up to 8 hours
 Non-Drowsy
 Non-Habitforming Formula

Compare to the Active Ingredient of
ROBITUSSIN® LONG-ACTING COUGHGELS™

28 Softgels
 NDC 58333-888-1

Warnings
 Do not use if you are taking a prescription medicine or over-the-counter (OTC) drug that contains MAO (i.e. heart drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAO drug. If you do not know if your prescription drug contains an MAO, ask a doctor or pharmacist before taking this product.

Directions
 Adults: Take 1 softgel 2 times a day, every 12 hours, with or without food. Do not take more than 2 softgels in 24 hours. Do not take more than 28 softgels in 28 days. Do not take more than 1 softgel at one time. Do not take more than 1 softgel every 6 hours. Do not take more than 8 softgels in 24 hours. Do not take more than 28 softgels in 28 days. Do not take more than 1 softgel at one time. Do not take more than 1 softgel every 6 hours. Do not take more than 8 softgels in 24 hours. Do not take more than 28 softgels in 28 days.

Other Information
 Contains 28 softgels.
 Each softgel contains 15 mg of dextromethorphan HBr.

Keep this and all other medications out of the reach of children. Use only as directed. Please consult your doctor if you have any questions.

ValuMed
 ADULT LONG-LASTING
COUGH RELIEF
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 COUGH SUPPRESSANT
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"This product is not manufactured or distributed by
 Pfizer, Inc., owner of the registered trademark
 Robitussin® Lingers Cold Long-Acting CoughGels®"

*Product may vary from image shown

DISTRIBUTED BY
 SPIRIT PHARMACEUTICALS, LLC.
 RONKONKOMA, NY 11779

ORG 07/17

VALUMEDS™

Compare to the active ingredient in Robitussin® Long Acting Cough Gels††

adult long lasting
COUGH RELIEF

Dextromethorphan
HBr, 15 mg

- ages 12+
- cough suppressant
- relieves cough for up to 8 hours
- non-drowsy / non-narcotic



60 softgels

Actual Size

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

Drug Facts

Active ingredient (in each softgel)

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

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- a cough that lasts or is chronic, as occurs with smoking, asthma, or emphysema

Drug Facts (continued under label)

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

Distributed by: Spirt Pharmaceuticals, LLC
Rockton, IL 61179

ITEM# 64726-2



Made in India

6 91036 64726 2

LOT:

EXP:



Drug Facts (continued)

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age	dose
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Inactive ingredients

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Questions or comments? 1-888-333-9792

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)	
GLYCERIN (UNII: PDC6A3C0OX)	
GELATIN (UNII: 2G86QN327L)	
SORBITOL (UNII: 506T60A25R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
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:68210-0106-1	1 in 1 CARTON	04/10/2018	
1		15 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:68210-0106-2	1 in 1 CARTON	03/12/2020	
2		240 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:68210-0106-3	1 in 1 CARTON	03/12/2020	
3		60 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	04/10/2018	

Labeler - Spirit Pharmaceuticals LLC (179621011)**Establishment**

Name	Address	ID/FEI	Business Operations
MEDGEL PVT LTD		677385498	manufacture(68210-0106)