DEXTROMETHORPHAN HYDROBROMIDE- dextromethorphan hydrobromide capsule, liquid filled Spirit Pharmaceuticals LLC

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	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

Distributed By:

SPIRIT PHARMACEUTICALS LLC.

RONKONKOMA, NY 11779

PRINCIPAL DISPLAY PANEL

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

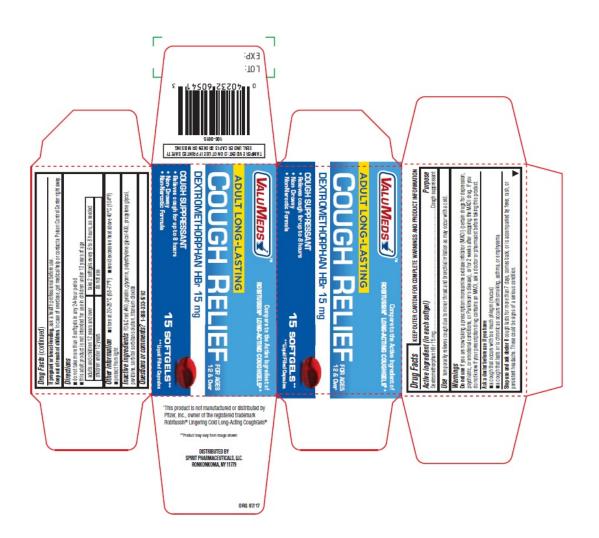
VALUMEDS™

ADULT LONG-LASTING Cough Relief FOR AGES 12 & OVER

Dextromethorphan HBr, 15 mg

Cough suppressant

Relieves cough for up to 8 hours





Compare to the active ingredient in - Robitussin[®] Long Acting Cough Gels^{®†}

adult long lasting

COUGH RELIEF

Dextromethorphan HBr, USP 15 mg

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

240 softgels



DEXTROMETHORPHAN HYDROBROMIDE

dextromethorphan hydrobromide capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-0106
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)		
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			

P	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		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	04/10/2018	

Labeler - Spirit Pharmaceuticals LLC (179621011)

Revised: 12/2023 Spirit Pharmaceuticals LLC