LONG ACTING COUGH SOFTGELS- dextromethorphan hydrobromide capsule, liquid filled CVS PHARMACY, INC

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.

Long Acting Cough Softgels

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 a doctor if cough lasts for more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These can be signs of a serious condition

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

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

	take 2 softgels 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

edible white ink, FD&C blue #1, FD&C red #40, gelatin, glycerin, isopropyl alcohol, medium chain triglycerides, polyethylene glycol, povidone, propyl gallate, propylene glycol, purified water, sorbitol sorbitan solution

Questions or comments?

1-888-577-8033 Monday-Friday

8am-4pm EST

CVS Health®

Compare to the active ingredient in Robitussin® CoughGels®**

Non-Drowsy

Controls cough

8 HOUR

READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSING FROM BOTTLE

**This product is not manufactured or distributed by Pfizer Consumer Healthcare LLC, owner of the registered trademark Robitussin[®] CoughGels[®].

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895 © 2021 CVS/pharmacy CVS.com® 1-800-SHOP CVS Product of UAE

CVS[®] Quality Money Back Guarantee

Packaging



LONG ACTING COUGH SOFTGELS

dextromethorphan hydrobromide capsule, liquid filled

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (S	ource)	NDC:5131	.6-778	
Route of Administration	ORAL					
Active Ingredient/Active	Majoty					
Active Ingredient/Active Moiety						
Ingredient Name			Basis of Str	ength	Strength	

DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH)

(DEXTROMETHORPHAN - UNII:7355X3ROTS)

WATER (UNII: 059QF0KOOR)

SORBITOL (UNII: 506T60A25R)

SORBITAN (UNII: 6092ICV9RU)

DEXTROMETHORPHAN HYDROBROMIDE

15 mg

Inactive Ingredients				
Ingredient Name	Strength			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				
ISOPROPYL ALCOHOL (UNII: ND2M416302)				
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)				
PROPYL GALLATE (UNII: 8D4SNN7V92)				
PROPYLENE GLYCOL (UNII: 6DC9O167V3)				

Product Characteristics				
Color	red	Score	no score	
Shape	OVAL	Size	14mm	
Flavor		Imprint Code	778	
Contains				

ı	Packaging						
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date			
:	NDC:51316-778- 23	1 in 1 CARTON	07/28/2021				
:	L	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	07/28/2021			

Labeler - CVS PHARMACY, INC (062312574)

Revised: 7/2023 CVS PHARMACY, INC