COUGH RELIEF- dextromethorphan hydrobromide capsule, liquid filled
Chain Drug Marketing Association 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-Lasting Cough Relief

Drug Facts

Active ingredient (in each softgel)

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 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

age	dose
adults and children 12 years and over	take 2 softgels every 6 to 8 hours, as needed
children under 12 years	do not use

Other information

- store at room temperature 15-30°C (59-86°F)
- avoid excessive heat above 40°C (104°F)
- protect from light

Inactive ingredients

FD&C blue #1, FD&C red #40, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution and white edible ink

Questions or comments?

Call toll free: **248-449-9300**

PRINCIPAL DISPLAY PANEL

ADULT LONG-LASTING Cough Relief

Dextromethorphan HBr, USP 15 mg 20 Softgels

NDC 63868-222-20

*Compare to the active ingredient in Robitussin® Lingering Cold Long-Acting CoughGels®

QUALITY CHOICE

Adult Long-Lasting

Cough Relief

Cough Suppressant

NDC 63868-222-20

QUALITY CHOICE

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Adult Long-Lasting

Cough Relief

Cough Suppressant

Dextromethorphan HBr, USP 15 mg

Relieves Cough for
Up to 8 Hours
Non- Drowsy
Non-Narcotic Formula

20 Liquid Gels (Liquid Filled Capsules)

KEEP OUTER CARTON FOR COMPLETE WARNING AND PRODUCT INFORMATION

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COUGH RELIEF

dextromethorphan hydrobromide capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-222
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 BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	red (clear)	**Score**	no score
Shape	capsule (oval)	**Size**	13mm
Flavor		**Imprint Code**	PC6
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-222-20	1 in 1 CARTON	07/13/2017	
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	07/13/2017	

Labeler - Chain Drug Marketing Association Inc. (011920774)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(63868-222) , analysis(63868-222)

Revised: 12/2019 Chain Drug Marketing Association Inc.