LONG ACTING COUGH SOFTGELS- dextromethorphan hbr 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.

Quality Choice 44-661

Active ingredient (in each liquid-filled capsule)

Dextromethorphan HBr, USP 15 mg

Purpose

Cough suppressant

Uses

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

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 (1-800-222-1222) 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 25°C (77°F); excursions permitted between 15°-30°C (59°-86°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, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol

Questions or comments?

1-800-426-9391

Principal display panel

QUALITY
CHOICE®

NDC 63868-447-20

*Compare to the
Active Ingredient in
Robitussin® CoughGels®

Long Acting Cough Softgels
Dextromethorphan HBr, USP 15 mg

Cough Suppressant
Up to 8 Hours | For Ages 12 & Over
Non-Drowsy | Non-Narcotic Formula

20 Softgels

actual size

*This product is not manufactured or distributed by Wyeth LLC, owner of the registered trademark Robitussin® CoughGels®.

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Product of China
Packaged and Quality Assured in the USA

Distributed by C.D.M.A., Inc.©
43157 W 9 Mile Rd
Novi, MI 48375
www.qualitychoice.com
Questions: 800-935-2362

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

Quality Choice 44-661

LONG ACTING COUGH SOFTGELS

dextromethorphan hbr capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-447
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)	

Product Characteristics

Color	RED (clear)	**Score**	no score
Shape	OVAL	**Size**	10mm
Flavor		**Imprint Code**	661
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-447-20	1 in 1 CARTON	08/07/2019	
1		20 in 1 BOTTLE, PLASTIC; 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	08/07/2019	

Labeler - CHAIN DRUG MARKETING ASSOCIATION INC (011920774)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(63868-447)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(63868-447)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(63868-447)

Revised: 6/2019 CHAIN DRUG MARKETING ASSOCIATION INC