

LONG ACTING COUGH SOFTGELS- 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.

QC® QUALITY CHOICE Adult Long Acting Cough Softgels

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 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

| | |
|--|---|
| adults and children 12 years and older | 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

Compare to the active ingredient in Robitussin® CoughGels®*

Relieves cough for up to 8 Hours
Non-Drowsy

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

Distributed by: C.D.M.A., Inc. ©
43157 W 9 Mile Rd Novi, MI 48375
www.qualitychoice.com
Product of UAE

Packaged and Quality Assured in the USA

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

100% QC SATISFACTION GUARANTEED

Packaging

INNER PACKAGE LABEL



NDC 63868-824-20

Compare to the active ingredient in Robitussin® CoughGels®*

Adult Long Acting Cough Softgels

Dextromethorphan HBr, USP 15 mg

Cough Suppressant
Relieves cough for up to 8 Hours
Non-Drowsy

20 SOFTGELS Actual Size

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No Varnish

Product of UAE
Packaged and Quality Assured in the USA
REV:00-072021
LB6386882420

LOT: _____
EXP: _____

OUTER PACKAGE LABEL

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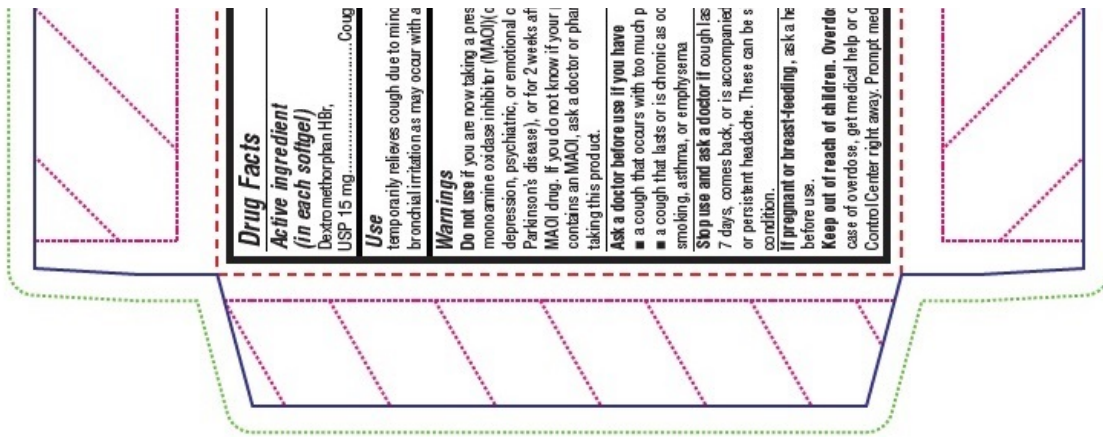
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No Varnish

LOT: _____
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DRUG FACTS TABLE

| | | | | | |
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LONG ACTING COUGH SOFTGELS

dextromethorphan hydrobromide capsule, liquid filled

Product Information

| | | | |
|---------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63868-824 |
|---------------------|----------------|---------------------------|---------------|

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, UNSPECIFIED (UNII: 2G86QN327L) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |
| PROPYL GALLATE (UNII: 8D45NN7V92) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| SORBITOL (UNII: 506T60A25R) | |
| SORBITAN (UNII: 6O92ICV9RU) | |

Product Characteristics

| | | | |
|-----------------|---------------|---------------------|----------|
| Color | red | Score | no score |
| Shape | OVAL (oblong) | Size | 14mm |
| Flavor | | Imprint Code | 778 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:63868-824-20 | 1 in 1 CARTON | 05/03/2022 | |
| 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 | 05/03/2022 | |

Revised: 7/2023

Chain Drug Marketing Association, Inc.