DEXTROMETHORPHAN HBR 15 MG LIQUID GELS- dextromethorphan hbr capsule, liquid filled
RUGBY LABORATORIES

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.

Dextromethorphan HBr USP 15 mg Liquid Gels

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 (1-800-222-1222). 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 gycol, purified water, sorbitol sorbitan solution

Questions or comments?

1-800-645-2158

Rugby®

Compare to the active ingredient in Robitussin® CoughGels®*

ADULT

Relieves:
Cough for up to 8 hours
Non-Drowsy

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, owner of the registered trademark Robitussin® CoughGels®.

Distributed by:
RUGBY® LABORATORIES
Livonia, MI 48152
www.rugbylaboratories.com

Product of UAE

Packaged and Quality
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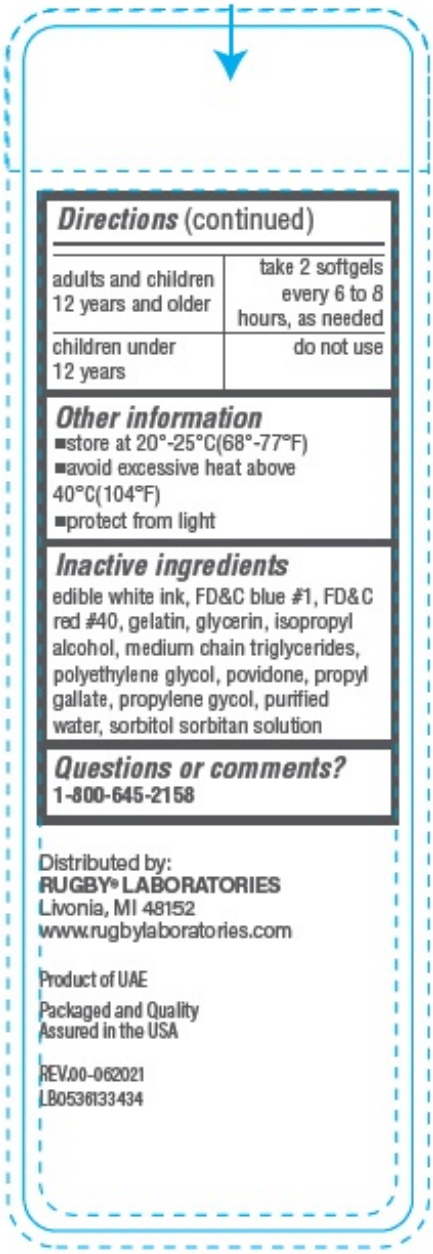
Packaging



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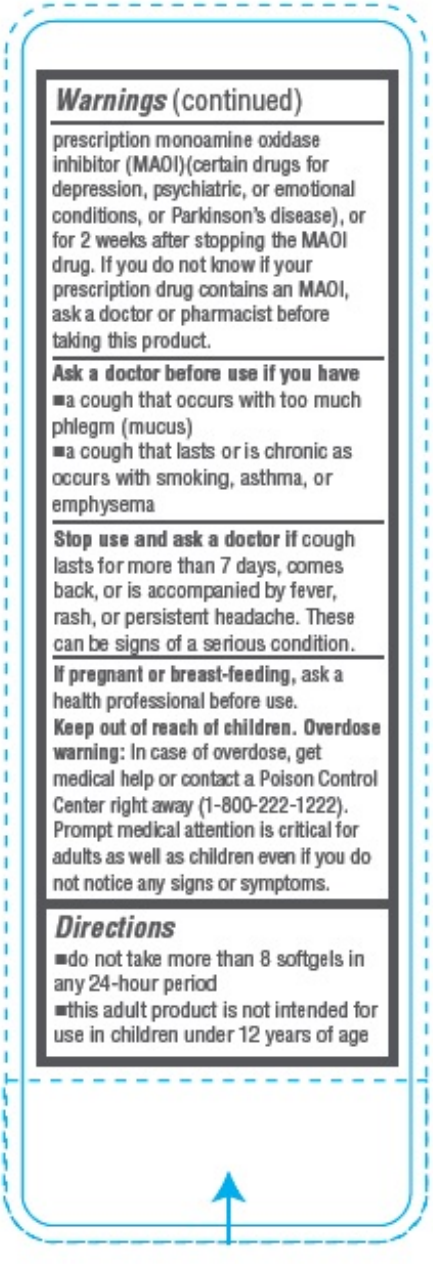

DEXTROMETHORPHAN HBR 15 MG LIQUID GELS

dextromethorphan hbr capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0536-1334
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: 3WQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	red	**Score**	no score
Shape	OVAL	**Size**	13mm
Flavor		**Imprint Code**	778
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1334-34	20 in 1 BOTTLE; Type 0: Not a Combination Product	09/04/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/04/2021	

Labeler - RUGBY LABORATORIES (079246066)

Revised: 7/2023 RUGBY LABORATORIES