

COUGH RELIEF- dextromethorphan hydrobromide capsule, liquid filled
Advanced Rx LLC

Cough Relief

Drug Facts

Active Ingredient (in each tablet)

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

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 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 between 20° and 25°C (68°–77°F)
- avoid excessive heat above 40°C (104°F)
- protect from light
- DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED

Inactive ingredients

Edible Ink, FD&C Red No. 40, Gelatin, Glycerin, Polyethylene Glycol 400, POLYSORB, Propylene Glycol, Purified Water, Povidone K30.

Questions?

Call **1-800-630-8895**

Distributed by:

Advanced Rx LLC
1942 NE 163rd St
North Miami Beach,
FL 33162 U.S.A.

NDC 80513-311-06

Cough Relief

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Compare to the active ingredient
in Robitussin® Long Acting Cough Gels®†

Non-Drowsy Formula

COUGH RELIEF

Dextromethorphan HBr, USP 15 mg

- ages 12+
- cough suppressant
- relieves cough for up to 8 hours

60
softgels

NDC 80513-311-06

DO NOT USE IF POINTED SEAL UNDER CAP IS MISSING OR DAMAGED

Drug Facts

Active ingredient (in each softgel) Purpose
Dextromethorphan HBr, USP 15 mg 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

PEEL FOR DIRECTIONS

Drug Facts (continued)
medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions
■ do not take more than 8 softgels in any 24-hour period
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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 between 20° and 25°C (68°–77°F)
■ avoid excessive heat above 40°C (104°F)
■ protect from light

Inactive ingredients
Edible Ink, FD&C Red 40, Gelatin, Glycerin, PEG 400, POLYSORB, Propylene glycol, Purified water, PVP K30.

Questions? call 1-800-630-8895

†This product is not manufactured or distributed by the owner of the registered trademark Robitussin® Long Acting Cough Gels®.

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North Miami Beach, FL 33162 U.S.A.

HINGE

COUGH RELIEF			
dextromethorphan hydrobromide capsule, liquid filled			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80513-311
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 RED NO. 40 (UNII: WZB9127XOA)			
GELATIN (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
POVIDONE K30 (UNII: U725QWY32X)			

WATER (UNII: 059QF0KO0R)

Product Characteristics

Color	red	Score	no score
Shape	OVAL	Size	13mm
Flavor		Imprint Code	904
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80513-311-06	60 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	01/01/2025	

Labeler - Advanced Rx LLC (042795108)

Establishment

Name	Address	ID/FEI	Business Operations
ELYSIUM PHARMACEUTICALS LIMITED		915664486	manufacture(80513-311)

Revised: 1/2025

Advanced Rx LLC