

DEXTROMETHORPHAN HYDROBROMIDE- dextromethorphan hydrobromide capsule, liquid filled
Softgel Healthcare Pvt Ltd

Dextromethorphan Hydrobromide Capsules, 15mg

Active ingredient (in each soft gelatin capsule)

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 capsules 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 capsules 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

FD & C Red no. 40, gelatin, glycerin, polyethylene glycol 400, povidone K 30, propyl gallate, propylene glycol, sorbital sorbitan solution, water

Do Not Use if foil is torn or missing.

Manufactured By

Softgel Healthcare Pvt. Ltd.,
Survey No. 20/1, Vandalur-Kelambakkam Road,
Pudupakkam Village, Kancheepuram District,
Tamilnadu - 603 103, India.
Mfg. Lic. No.:XXXXXXXXXXXX

Principal Display Panel

ADULT

NDC 35916-0461-1

*Compared to the active ingredients in Robitussin[®] Long-Acting CoughGels[®]

Dextromethorphan Hydrobromide Capsules, 15mg

(Cough Suppressant)

20 Softgels

Liquid Filled Capsules

Upto

8

hour

relief

Non-Drowsy Formula

For Ages 12 & Over

FRONT PAGE
Multilayer Roll Direction



30 mm

ADULT
NDC 35916-0461-1

*Compared to the active ingredient in Robitussin® Long - Acting CoughGels®

Dextromethorphan Hydrobromide
Capsules, 15mg
(Cough Suppressant)

UPTO
8
HOUR
RELIEF

Liquor Filled Capsules

Non-Drowsy Formula
For Ages 12 & Over

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USP, 15 mg

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Vandalur-Keelambakkam Road,
Pudupakkam Village,
Kancheepuram District,
Tamilnadu - 603 103, India.

Mfg. Lic. No. XXXXXXXXXX

unvarnished Area
for 2D Barcode &
Batch Details
LH - 25 x 20 mm

Peel here

100 mm

Back

30 mm

**8 mm
Blank
for
Glue
Area**

Drug facts (continued)

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*This product is not manufactured or distributed by Pfizer, owner of the registered trademark Robitussin® Long - Acting CoughGels®

**8 mm
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for
Glue
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100 mm

DEXTROMETHORPHAN HYDROBROMIDE

dextromethorphan hydrobromide capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35916-0461
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE K30 (UNII: U725QWY32X)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color	red (Transparent)	Score	no score
Shape	OVAL	Size	13mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35916-0461-1	20 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	09/11/2024	

Labeler - Softgel Healthcare Pvt Ltd (675584180)

Revised: 9/2024

Softgel Healthcare Pvt Ltd