

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

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**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

<b>age</b>	<b>dose</b>
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, purified water, sorbital sorbitan solution

## Manufactured By

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

<b><u>DEXTROMETHORPHAN HYDROBROMIDE CAPSULES, 15 MG</u></b> Each Soft Gelatin Capsule Contains: (Dextromethorphan Hydrobromide USP 15 mg)		Imprint
BATCH NO : MFG DATE : EXP DATE : QUANTITY :	NDC NO : 35916-0461- 4 GROSS WT : NET WT : SHIPPER NO. :	
<b><u>WARNING :</u></b> <b>KEEP OUT OF REACH OF CHILDREN</b>		
<b><u>STORAGE</u></b> STORE AT 20 – 25°C (68 – 77°F). AVOID EXCESSIVE HEAT ABOVE 40°C (104°F). PROTECT FROM LIGHT.		
THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY. CONTENTS SHOULD BE APPROVED, REPACKED IMMEDIATELY AND LABELED IN STRICT CONFORMANCE WITH THE FD&C ACT AND REGULATIONS.		
<b>MANUFACTURED BY:</b> <b>SOFTGEL HEALTHCARE PVT. LTD.,</b> SURVEY NO. 20/1, VANDALUR – KELAMBAKKAM ROAD, PUDUPAKKAM , CHENGALPATTU, TAMILNADU 603 103, INDIA (IND) LABELLER CODE: 35916 LIC NO: XXXX	<b>MANUFACTURED FOR</b>	
<b><u>CAUTION : "FOR MANUFACTURING, PROCESSING OR REPACKAGING"</u></b>		

# FRONT PAGE

## Multilayer Roll Direction



30 mm

<p><b>ADULT</b> <span style="float: right;">NDC 35916-0461-1</span></p> <p><small>*Compared to the active ingredient in Robitussin® Long - Acting CoughGels®</small></p> <p style="text-align: center;"><b>Dextromethorphan Hydrobromide Capsules, 15mg</b> (Cough Suppressant)</p> <div style="text-align: center;">  <p><b>UPTO 8 HOUR RELIEF</b></p> </div> <p style="text-align: center;"><b>20 Softgels</b> <small>Liquid Filled Capsules</small></p> <p style="text-align: right;"><b>Non-Drowsy Formula</b> <small>For Ages 12 &amp; Over</small></p>	<p><b>Drug Facts</b></p> <p><b>Active ingredient</b> (in each soft gelatin capsule) dextromethorphan Hbr USP 15 mg</p>	<p><b>Purpose</b> Cough suppressant</p>	<p><b>Use</b> Temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold.</p>	<p><b>Warnings</b> <b>Do not use</b> 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.</p>	<p><b>Manufactured by:</b> <b>SoftGel Healthcare Pvt. Ltd.,</b> Survey No. 20/1, Vandalur-Keelambakkam Road, Pudupakkam Village, Kancheepuram District, Tamilnadu - 603 103, India.</p> <div style="text-align: right;">   <small>Mfg. Lic. No. XXXXXXXXXX</small> </div>
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100 mm

## Back

30 mm

<b>8 mm Blank for Glue Area</b>	<p><b>Drug facts (continued)</b></p> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>■ a cough that occurs with too much phlegm (mucus)</li> <li>■ a cough that lasts or is chronic as occurs with smoking, asthma, or emphysema</li> </ul> <p><b>Stop use and ask a doctor if</b></p> <p>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.</p> <p><b>If pregnant or breast-feeding,</b> ask a health professional before use.</p> <p><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>■ do not take more than 8 capsules in any 24-hour period</li> <li>■ this adult product is not intended for use in children under 12 years of age</li> </ul> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <thead> <tr> <th style="width: 30%;">age</th> <th style="width: 70%;">dose</th> </tr> </thead> <tbody> <tr> <td>adults and children 12 years and over</td> <td>take 2 capsules every 6 to 8 hours, as needed</td> </tr> <tr> <td>children under 12 years</td> <td>do not use</td> </tr> </tbody> </table> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>■ store at 20-25°C (68-77°F)</li> <li>■ avoid excessive heat above 40°C (104°F)</li> <li>■ protect from light</li> </ul> <p><b>Inactive ingredients</b> FD &amp; C red no. 40, gelatin, glycerin, polyethylene glycol 400, povidone K 30, propyl galate, propylene glycol, sorbitol sorbitan solution, water</p> <p><small>*This product is not manufactured or distributed by Pfizer, owner of the registered trademark Robitussin® Long - Acting CoughGels®</small></p>	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	<b>8 mm Blank for Glue Area</b>
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adults and children 12 years and over	take 2 capsules every 6 to 8 hours, as needed							
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100 mm

<b><u>DEXTROMETHORPHAN HYDROBROMIDE CAPSULES, 15 MG</u></b> Each Soft Gelatin Capsule Contains: (Dextromethorphan HBr USP 15 mg)		Imprint		
BATCH NO	:	NDC NO	:	35916-0461- 3
MFG DATE	:	GROSS WT	:	
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QUANTITY	:	SHIPPER NO.	:	
<b><u>WARNING :</u></b> <b>KEEP OUT OF REACH OF CHILDREN</b>				
<b><u>STORAGE</u></b> STORE AT 20 – 25°C (68 – 77°F). AVOID EXCESSIVE HEAT ABOVE 40°C (104°F). PROTECT FROM LIGHT.				
THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY. CONTENTS SHOULD BE APPROVED, REPACKED IMMEDIATELY AND LABELED IN STRICT CONFORMANCE WITH THE FD&C ACT AND REGULATIONS.				
<b>MANUFACTURED BY:</b> <b>SOFTGEL HEALTHCARE PVT. LTD.,</b> SURVEY NO. 20/1, VANDALUR – KELAMBAKKAM ROAD, PUDUPAKKAM , CHENGALPATTU, TAMILNADU 603 103, INDIA (IND) LABELLER CODE: 35916 LIC NO: XXXX		<b>MANUFACTURED FOR</b>		
<b><u>CAUTION : “FOR MANUFACTURING, PROCESSING OR REPACKAGING”</u></b>				

<b><u>DEXTROMETHORPHAN HYDROBROMIDE CAPSULES, 15 MG</u></b>		Imprint
Each Soft Gelatin Capsule Contains: (Dextromethorphan HBr USP 15 mg)		
BATCH NO :	NDC NO :	35916-0461-2
MFG DATE :	GROSS WT :	
EXP DATE :	NET WT :	
QUANTITY :	SHIPPER NO. :	
<b><u>WARNING :</u></b> <b>KEEP OUT OF REACH OF CHILDREN</b>		
<b><u>STORAGE</u></b> STORE AT 20 – 25°C (68 – 77°F). AVOID EXCESSIVE HEAT ABOVE 40°C (104°F). PROTECT FROM LIGHT.		
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<b><u>CAUTION : “FOR MANUFACTURING, PROCESSING OR REPACKAGING”</u></b>		

## DEXTROMETHORPHAN HYDROBROMIDE

dextromethorphan hydrobromide capsule, liquid filled

### Product Information

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

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII: 7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>PROPYL GALLATE</b> (UNII: 8D45NN7V92)	
<b>WATER</b> (UNII: 059QF0KO0R)	

<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	

### Product Characteristics

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

### 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	
2	NDC:35916-0461-2	1000 in 1 BAG; Type 0: Not a Combination Product	03/18/2025	
3	NDC:35916-0461-3	2 in 1 BOX	07/17/2025	
3		3000 in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:35916-0461-4	2 in 1 BOX	01/12/2026	
4		1500 in 1 BAG; Type 0: Not a Combination Product		

### 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 (676666501)

Revised: 1/2026

Softgel Healthcare Pvt Ltd