

**DEXTROMETHORPHAN HBR,GUAIFENESIN- dextromethorphan  
hbr,guaifenesin capsule, liquid filled  
Softgel Healthcare Pvt Ltd**

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**Dextromethorphan Hydrobromide 10 mg and Guaifenesin 200 mg Softgelatin  
Capsules**

***Active ingredient (in each soft gelatin capsule)***

Dextromethorphan HBr USP 10mg

Guaifenesin USP 200mg

***Purposes***

Cough suppressant

Expectorant

***Uses***

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
- cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
- the intensity of coughing
- the impulse to cough to help you get to sleep

***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**

- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm(mucus)

**When using this product do not use more than directed**

**Stop use and ask a doctor if**

- cough lasts more than 7 days, comes back, or occur with fever, rash, or headache that lasts.

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 12 liquid gels in any 24-hour period
- adults and children 12 years of age and over: take 2 liquid gels every 4 hours
- children under 12 years of age: do not use

**Other information**

- store at 20-25°C (68-77°F)
- avoid excessive heat

**Inactive ingredients**

D&C yellow 10, FD&C blue 1, gelatin, glycerin, polyethylene glycol 400, povidone k-30, purified water, sorbitol sorbitan solution, titanium dioxide

**Bulk package label**

<p><b><u>DEXTROMETHORPHAN HYDROBROMIDE 10 MG AND GUAIFENESIN 200 MG</u></b>  <b><u>SOFTGELATIN CAPSULES</u></b>                  Each Soft Gelatin Capsule Contains:                  Dextromethorphan Hydrobromide USP 10 mg and Guaifenesin USP 200 mg</p>		<p>Imprint</p>
<p>BATCH NO :                  MFG DATE :                  EXP DATE :                  QUANTITY :</p>	<p>NDC NO : 35916-0760-1                  GROSS WT :                  NET WT :                  SHIPPER NO. :</p>	
<p><b><u>WARNING: KEEP OUT OF REACH OF CHILDREN</u></b></p>		
<p><b><u>STORAGE</u></b>                  STORED AT 20-25°C (68-77°F)</p>		
<p>THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY.                  CONTENTS SHOULD BE APPROVED, REPACKED IMMEDIATELY AND LABELED IN STRICT CONFORMANCE WITH THE                  FD&amp;C ACT AND REGULATIONS.</p>		
<p><b>MANUFACTURED BY:</b>                  SOFTGEL HEALTHCARE PVT. LTD.,                  SURVEY NO. 20/1, VANDALUR – KELAMBAKKAM ROAD,                  PUDUPAKKAM VILLAGE, KANCHEEPURAM,                  TAMILNADU 603 103, INDIA (IND)                  LABELLER CODE:35916                  LIC NO: XXXX</p>	<p><b>MANUFACTURED FOR</b></p>	
<p><b>CAUTION: “FOR MANUFACTURING, PROCESSING OR REPACKING”</b></p>		

<p><b>DEXTROMETHORPHAN HBR,GUAIFENESIN</b>                  dextromethorphan hbr,guaifenesin capsule, liquid filled</p>			
<p><b>Product Information</b></p>			
<p><b>Product Type</b></p>	<p>HUMAN OTC DRUG</p>	<p><b>Item Code (Source)</b></p>	<p>NDC:35916-0760</p>

<b>Route of Administration</b>	ORAL			
<b>Active Ingredient/Active Moiety</b>				
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
	<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg	
	<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
<b>Inactive Ingredients</b>				
	<b>Ingredient Name</b>	<b>Strength</b>		
	<b>GLYCERIN</b> (UNII: PDC6A3C0OX)			
	<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)			
	<b>SORBITOL</b> (UNII: 506T60A25R)			
	<b>WATER</b> (UNII: 059QF0KO0R)			
	<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)			
	<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)			
	<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)			
	<b>GELATIN</b> (UNII: 2G86QN327L)			
	<b>POVIDONE K30</b> (UNII: U725QWY32X)			
<b>Product Characteristics</b>				
<b>Color</b>	green (Opaque)	<b>Score</b>	no score	
<b>Shape</b>	OVAL	<b>Size</b>	16mm	
<b>Flavor</b>		<b>Imprint Code</b>		
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:35916-0760-1	1000 in 1 BAG; Type 0: Not a Combination Product	03/21/2025	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC Monograph Drug	M012	03/21/2025		

**Labeler** - Softgel Healthcare Pvt Ltd (675584180)