

**DEXTROMETHORPHAN HBR,GUAIFENESIN- dextromethorphan  
hbr,guaifenesin capsule, liquid filled  
SOFTGEL HEALTHCARE PRIVATE LIMITED**

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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

<u><b>DEXTROMETHORPHAN HYDROBROMIDE 10 MG AND GUAIFENESIN</b></u> <u><b>200 MG SOFTGELATIN CAPSULES</b></u> Each Soft Gelatin Capsule Contains: Dextromethorphan Hydrobromide USP 10 mg and Guaifenesin USP 200 mg		Imprint
BATCH NO :		NDC NO : 35916-0760-1
MFG DATE :		GROSS WT :
EXP DATE :		NET WT :
QUANTITY :		SHIPPER NO. :
<b>WARNING: KEEP OUT OF REACH OF CHILDREN</b>		
<u><b>STORAGE</b></u> STORED AT 20-25°C (68-77°F)		
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>CAUTION: "FOR MANUFACTURING, PROCESSING OR REPACKING"</b>		

**DEXTROMETHORPHAN HBR, GUAIFENESIN**

dextromethorphan hbr, guaifenesin capsule, liquid filled

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:35916-0760
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

**Inactive Ingredients**

Ingredient Name	Strength
<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)	

**Product Characteristics**

<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>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35916-0760-1	1000 in 1 BAG; Type 0: Not a Combination Product	03/21/2025	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	03/21/2025	

**Labeler** - SOFTGEL HEALTHCARE PRIVATE LIMITED (676666501)

Revised: 1/2026

SOFTGEL HEALTHCARE PRIVATE LIMITED