

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

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**Guaifenesin 400 mg and Dextromethorphan Hydrobromide 20 mg Softgelatin Capsules**

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

Guaifenesin USP 400mg

Dextromethorphan HBr USP 20mg

***Purposes***

Expectorant

Cough suppressant

***Uses***

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

***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**

- cough accompanied by excessive phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema

**When using this product**

- do not exceed recommended dosage
- do not use for more than 7 days

**Stop use and ask a doctor if**

- cough lasts for more than 7 days, recurs, 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 accidental overdose, get medical help or

contact a Poison Control Center right away.

### **Directions**

- do not exceed 6 doses in 24 hours
- take with a full glass of water
- **adults and children 12 years of age and over:** take 1 softgel every 4 hours
- **children under 12 years of age:** do not use

### **Other information**

- store at 25°C (77°F); excursions permitted between 15° -30°C (59° -86°F)
- Keep in dry place and do not expose to heat

### **Inactive ingredients**

gelatin, glycerin, polyethylene glycol 400, povidone k-30, propylene glycol, purified water, sorbitol sorbitan solution

### **Bulk package label**

<b><u>GUAIFENESIN 400 MG AND DEXTROMETHORPHAN HYDROBROMIDE 20</u></b> <b><u>MG SOFT GELATIN CAPSULES,</u></b> <u>Each Soft Gelatin Capsule Contains:</u> Guaifenesin USP 400 mg and Dextromethorphan Hydrobromide USP 20 mg		Imprint
BATCH NO :	NDC NO :	35916-0759-2
GROSS WT :	MFG DATE :	
NET WT :	EXP DATE :	
QUANTITY :	SHIPPER NO. :	
<b><u>WARNING : KEEP OUT OF REACH OF CHILDREN</u></b>		
<b><u>STORAGE</u></b> STORED AT 25°C (77°F); EXCURSIONS PERMITTED BETWEEN 15°- 30°C (59° - 86°F)		
THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY. CONTENTS SHOULD BE APPROVED, REPACKED IMMEDIATELY (9 MONTHS FROM MFG. DT.) 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 VILLAGE, KANCHEEPURAM, TAMILNADU 603 103, INDIA (IND) LABELLER CODE:35916 LIC NO:XXXX		<b>MANUFACTURED FOR</b>
<b>CAUTION : “FOR MANUFACTURING, PROCESSING OR REPACKING”</b>		

## **GUAIFENESIN, DEXTROMETHORPHAN HBR**

guaifenesin, dextromethorphan hbr capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35916-0759
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg

Inactive Ingredients	
Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	

Product Characteristics			
Color	yellow (Clear transparent)	Score	no score
Shape	CAPSULE (Oblong)	Size	22mm
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35916-0759-2	2 in 1 BOX	07/11/2025	
1		3000 in 1 POUCH; 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	07/11/2025	

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

