

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

**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

<u>GUAIFENESIN 400 MG AND DEXTROMETHORPHAN HYDROBROMIDE 20 MG</u> <u>SOFT GELATIN CAPSULES,</u> Each Soft Gelatin Capsule Contains: Guaifenesin USP 400 mg and Dextromethorphan Hydrobromide USP 20 mg		Imprint
BATCH NO :	NDC NO :	35916-0759-4
GROSS WT :	MFG DATE :	
NET WT :	EXP DATE :	
QUANTITY :	SHIPPER NO. :	
<u>WARNING : KEEP OUT OF REACH OF CHILDREN</u>		
<u>STORAGE</u> 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.		
MANUFACTURED BY: SOFTGEL HEALTHCARE PVT. LTD., SURVEY NO. 20/1, VANDALUR – KELAMBAKKAM ROAD, PUDUPAKKAM, CHENGALPATTU, TAMILNADU 603 103, INDIA (IND) LABELLER CODE:35916 LIC NO:XXXX	MANUFACTURED FOR	
CAUTION : “FOR MANUFACTURING, PROCESSING OR REPACKING”		

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
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
GELATIN (UNII: 2G86QN327L)	
POVIDONE K30 (UNII: U725QWY32X)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (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:35916-0759-3	2 in 1 BOX	09/15/2025	
1		2000 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:35916-0759-4	2 in 1 BOX	01/13/2026	
2		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	09/11/2025	

Labeler - Softgel Healthcare Pvt Ltd (676666501)