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 accompained 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>GUAII</u> | ENESIN 400 MG AND DEXTROMETHORPHAN HYDROBROMIDE 20 MG SOFT GELATIN CAPSULES, Each Soft Gelatin Capsule Contains: Guaifenesin USP 400 mg and Dextromethorphan Hydrobromide USP 20 mg | Imprint |
|---|---|----------|
| BATCH NO : | NDC NO : 35916-0759-3 | ı |
| GROSS WT : | MFG DATE : | |
| NET WT : QUANTITY : | EXP DATE : SHIPPER NO : | |
| QUANTITI . | WARNING: KEEP OUT OF REACH OF CHILDREN | |
| CONTENTS SHOUL | THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY. D BE APPROVED, REPACKED IMMEDIATELY (9 MONTHS FROM MFG. DT.) AND LABELED IN CONFORMANCE WITH THE FD&C ACT AND REGULATIONS. | N STRICT |
| MANUFACTURED B | | |
| SOFTGEL HEALTHO | | |
| SURVEY NO. 20/1, VANDALUR – KELAMBAKKAM ROAD, | | |
| PUDUPAKKAM VILLAGE, KANCHEEPURAM, | | |
| TAMILNADU 603 103, INDIA (IND) | | |
| LABELLER CODE:35916 | | |
| LIC NO:XXXX | | |
| (| AUTION: "FOR MANUFACTURING, PROCESSING OR REPACKING" | |

bulk label

GUAIFENESIN, DEXTROMETHORPHAN HBR guaifenesin, dextromethorphan hbr capsule, liquid filled Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:35916-0759

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

| I | Packaging | | | |
|---|----------------------|--|-------------------------|-----------------------|
| | # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| | NDC:35916- 0759-3 | 2 in 1 BOX | 09/15/2025 | |
| | 1 | 2000 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 | 09/11/2025 | |
| | | | |

Labeler - Softgel Healthcare Pvt Ltd (675584180)

Revised: 9/2025 Softgel Healthcare Pvt Ltd