

CHEST CONGESTION RELIEF- guaifenesin and dextromethorphan hbr tablet
Mckesson

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Guaifenesin 400 mg

Active Ingredient

(in each intermediate release tablet)

Guaifenesin 400 mg

Dextromethorphan HBr 20 mg

Purpose

Expectorant

Cough Suppressant

Uses

- temporarily relieves cough due to minor throat and bronchial irritation associated with the common cold
- helps loosen phelgm (mucus) and thin bronchial secretions to 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 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 too much of phelgm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- when using this product do not use more than directed

Stop use and ask doctor if

Cough lasts more than 7 days, comes back, or occurs with 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 overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- take with full glass of water;

1 tablet every 4 hours

- do not take more than 6 tablets in 24 hours
- children under 12 years: do not use

Other Information

- store at 25° C(77°F) ; excursion permitted between 15°-30° C (59°-86°F)
- see end flap for expiration date and lot number
- metal content per tablet:
- sodium 7mg, Magnesium 1mg

Inactive Ingredients

Colloidal Silicon Dioxide, Hypromellose, Microcrystalline cellulose, Magnesium stearate, Polyethylene Glycol, Stearic Acid powder, Sodium Starch Glycolate

Questions or Comments

Call 1-855-314-1850

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

sunmark[®]
NDC 70677-0012-1

chest congestion relief **DM** Cough Suppressant Expectorant

GUAIFENESIN 400 mg
DEXTROMETHORPHAN HBr 20 mg
MUCUS RELIEF
50 CAPLETS



Drug Facts

Active Ingredients (in each headed white oval) **Purpose**
Guaifenesin 400 mg.....Expectorant
Dextromethorphan HBr 20 mg.....Cough suppressant

- Uses**
- temporarily relieves cough due to minor throat and bronchial irritation associated with the common cold
 - helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

Warnings

- Do not use if you are now taking a prescription, nonprescription, or over-the-counter (OTC) cough suppressant, expectorant, or decongestant (including pseudoephedrine or phenylephrine), or if you are taking a prescription drug containing an MAOI, ask a doctor or pharmacist before taking this product.
- Ask a doctor before use if you have

- cough accompanied by too much phlegm (mucus)
 - persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- When using this product, do not use more than directed. Stop use and ask a doctor if cough lasts more than 7 days, worsens, or occurs with fever, rash, or persistent headache. These could be signs of a serious condition.

Drug Facts (continued)

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 (1-800-222-1222) right away.

Directions

- Take with a full glass of water
- adults and children 12 years of age and over: 1 caplet every 4 hours.
- Do not take more than 6 caplets in 24 hours.
- children under 12 years: do not use

Other Information

- Store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- Please do not use if safety seal inside the bottle is missing or broken.

Questions or comments?
call toll free 1-855-514-1830

**READ AND KEEP CARTON FOR COMPLETE
WARNINGS AND INFORMATION**

Made in India

MCKESSON

Another Quality Product Distributed By McKesson
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Money Back Guarantee
Please visit us at www.sunmarkbrand.com



NDC 70677-0012-1

CHEST CONGESTION RELIEF

guaifenesin and dextromethorphan hbr tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70677-0012
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

Product Characteristics

Color	WHITE	Score	no score
Shape	CAPSULE	Size	16mm
Flavor		Imprint Code	TCL;280
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677-0012-1	50 in 1 BOTTLE	11/25/2016	
1		1 in 1 CARTON; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	11/25/2016	

Labeler - Mckesson (177667227)

Revised: 12/2016

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