

TOPCARE MUCUS ER- guaifenesin tablet, multilayer, extended release
Topco Associates LLC

Topco Associates LLC. Mucus ER Drug Facts

Active ingredient (in each extended-release tablet)

Guaifenesin 600 mg

Purpose

Expectorant

Uses

- 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

- for children under 12 years of age

Ask a doctor before use if you have

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

Stop use and ask a 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 illness.

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

- do not crush, chew, or break tablet
- take with a full glass of water
- this product can be administered without regard for the timing of meals
- adults and children 12 years of age and over: 1 or 2 tablets every 12 hours. Do not exceed 4 tablets in 24 hours.
- children under 12 years of age: do not use

Other information

- store at 20-25°C (68-77°F)

Inactive ingredients

carbomer homopolymer type B, FD&C blue #1 aluminum lake, hypromellose, magnesium stearate,

microcrystalline cellulose, sodium starch glycolate

Questions or comments?

1-888-423-0139

Package/Label Principal Display Panel

TopCare® health

COMPARE TO MUCINEX® ACTIVE INGREDIENT

Mucus ER

GUAIFENESIN

EXTENDED-RELEASE TABLETS, 600 mg

EXPECTORANT

12 HOUR

- Relieves Chest Congestion
- Thins and Loosens Mucus
- Immediate and Extended Release

40 EXTENDED-RELEASE TABLETS

actual size



TOPCARE MUCUS ER
guaifenesin tablet, multilayer, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76162-123
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	600 mg

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL OR ALLYL SUCROSE CROSSLINKED) (UNII: K6MOM3T5YL)	

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

Color	BLUE	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	L2X2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76162-123-58	1 in 1 CARTON	09/29/2022	
1		40 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078912	09/29/2022	

Labeler - Topco Associates LLC (006935977)

Revised: 10/2022

Topco Associates LLC