

**TOPCARE MUCUS D- guaifenesin and pseudoephedrine hydrochloride tablet,  
multilayer, extended release  
Topco Associates LLC**

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**Topco Associates LLC. Mucus-D Drug Facts**

**Active ingredients (in each extended-release bi-layer tablet)**

Guaifenesin 600 mg

Pseudoephedrine HCl 60 mg

**Purposes**

Expectorant

Nasal Decongestant

**Uses**

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves nasal congestion due to:
  - common cold
  - hay fever
  - upper respiratory allergies
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage
- temporarily relieves sinus congestion and pressure

**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**

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

- cough accompanied by too much phlegm (mucus)

### **When using this product**

- do not use more than directed

### **Stop use and ask a doctor if**

- you get nervous, dizzy, or sleepless
- symptoms do not get better within 7 days, come back or occur with a 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 timing of meals
- adults and children 12 years and older: 2 tablets every 12 hours; not more than 4 tablets in 24 hours
- children under 12 years of age: do not use

### **Other information**

- **do not use if printed blister unit is broken or torn**
- store between 20-25°C (68-77°F)

### **Inactive ingredients**

carbomer homopolymer type B, colloidal silicon dioxide, FD&C yellow #6 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® D ACTIVE INGREDIENTS

Mucus-D

GUAIFENESIN 600 mg

PSEUDOEPHEDRINE HYDROCHLORIDE 60 mg

EXTENDED-RELEASE BI-LAYER TABLETS

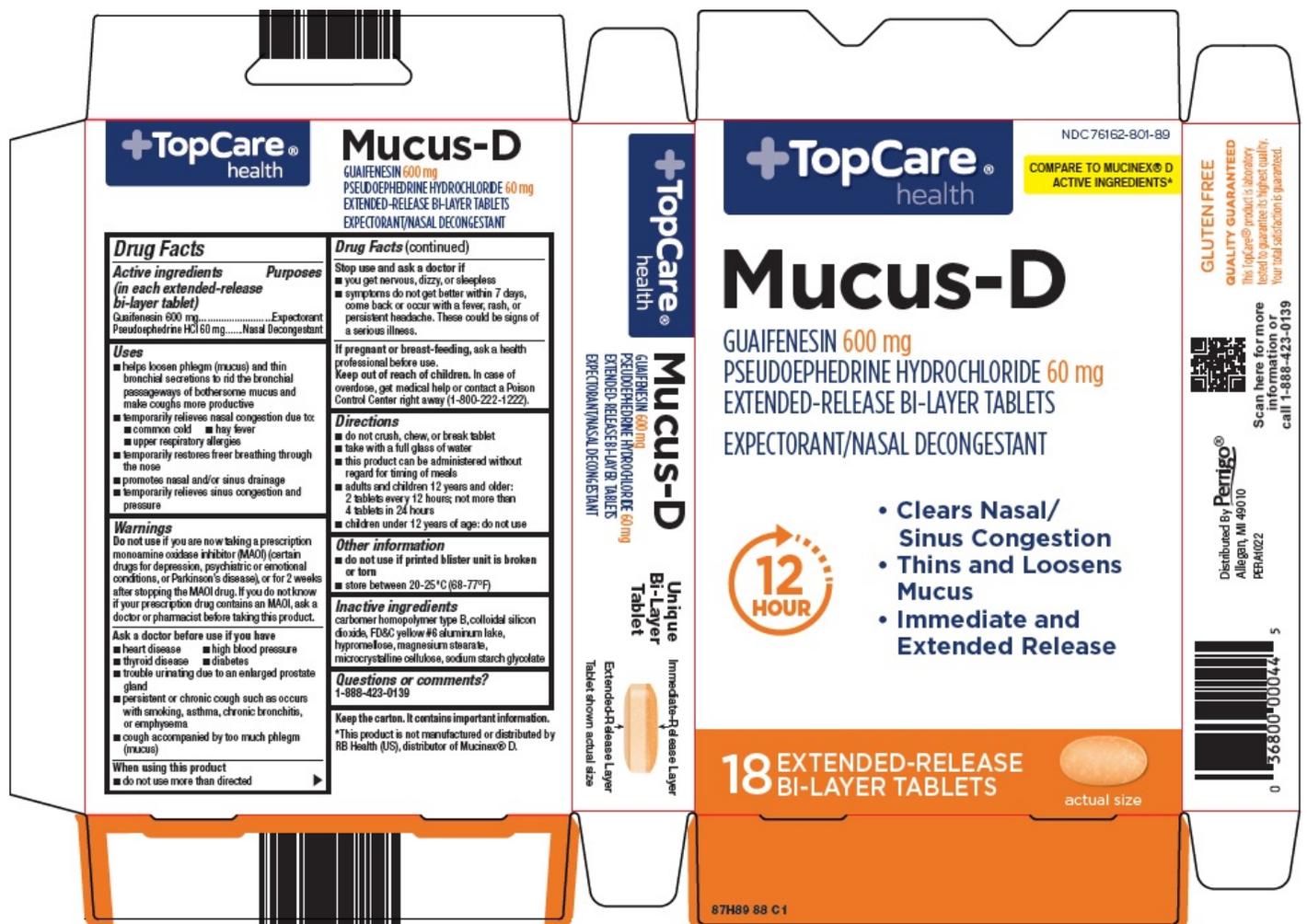
EXPECTORANT/NASAL DECONGESTANT

12 HOUR

- Clears Nasal/Sinus Congestion
- Thins And Loosens Mucus
- Immediate and Extended Release

18 EXTENDED-RELEASE BI-LAYER TABLETS

actual size



## TOPCARE MUCUS D

guaifenesin and pseudoephedrine hydrochloride tablet, multilayer, extended release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76162-801
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	600 mg
<b>PSEUDOEPHEDRINE HYDROCHLORIDE</b> (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	60 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: HHT01Z NK31)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	

## Product Characteristics

<b>Color</b>	ORANGE	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	L6
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:76162-801-89	18 in 1 CARTON	08/16/2023	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA214407	08/16/2023	

**Labeler** - Topco Associates LLC (006935977)