

MUCOSA DM- guaifenesin dextromethorphan tablet
TIME CAP LABORATORIES, INC.

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.

280R Timely 49483-280 Dextromethorphan HBr 20 mg and Guaifenesin 400 mg Tablets

Active ingredients (in each immediate-release tablet)

Dextromethorphan HBr 20 mg

Guaifenesin 400 mg

Purpose

Cough suppressant

Expectorant

Uses

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

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 healthcare 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

- adults and children 12 years of age and older: take 1 tablet every 4 hours with a full glass of water while symptoms persist. Do not exceed 6 doses in 24 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 a dry place and do not expose to excessive heat

Inactive ingredients colloidal silicon dioxide, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, silicon dioxide, sodium starch glycolate, stearic acid

Questions or comments?

Call **1-877-290-4008**

Adhesive Area

<p>Drug Facts (continued)</p> <p>When using this product</p> <ul style="list-style-type: none"> ■ do not exceed recommended dosage ■ do not use for more than 7 days <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ 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. <p>If pregnant or breast-feeding, ask a healthcare professional before use.</p> <p>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.</p> <p>Directions</p> <ul style="list-style-type: none"> ■ adults and children 12 years of age and older: take 1 tablet every 4 hours with a full glass of water while symptoms persist. Do not exceed 6 doses in 24 hours. ■ children under 12 years of age: do not use <p>Other information</p> <ul style="list-style-type: none"> ■ store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F) ■ keep in a dry place and do not expose to excessive heat <p>Inactive ingredients</p> <p>colloidal silicon dioxide, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, silicon dioxide, sodium starch glycolate, stearic acid</p> <p>Questions or comments? Call 1-877-290-4008</p>

NDC 49483-280-20

Immediate-Release

Mucus Relief DM

Dextromethorphan HBr 20 mg
Guaifenesin 400 mg

COUGH SUPPRESSANT & EXPECTORANT

- Controls Cough
- Thins and Loosens Mucus

200 TABLETS

TCL 280

Actual Size

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING

Drug Facts

Active ingredients

Purpose
(In each immediate-release tablet)

Dextromethorphan HBr 20 mg.....Cough suppressant

Guaifenesin 400 mg.....Expectorant

Uses

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

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

Drug Facts (continued under label)

Manufactured by:
Time-Cap Labs, Inc.
7 Michael Avenue Farmingdale,
NY 11735
280R 0823

3 14948312802013

Varnish Omit Area

Lot No: _____
Exp Date: _____

PEEL HERE

PEEL HERE FOR MORE DRUG FACTS

LOT #: EXP. DATE:

Drug Facts
(in each immediate-release tablet)

Active Ingredients
Purpose
Dextromethorphan
HBr 20 mg.....Cough suppressant
Guaifenesin 400 mg.....Expectorant

Uses
■ helps loosen phlegm (mucus)
■ helps thin bronchial secretions to make coughs more productive

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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



TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING

Manufactured by Time-Cap Labs, Inc.
7 Michael Avenue, Farmingdale, NY 11735 280R 1009

NDC 49483-2800-06
Time-Cap Labs, Inc.



Drug Facts (continued)
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
■ cough lasts for more than 7 days, recurs, or stop use and ask a doctor if is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a healthcare professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

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STOP PEELING

MUCOSA DM

guaifenesin dextromethorphan tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-280
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)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	16mm
Flavor		Imprint Code	TCL280
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-280-06	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/17/2018	
2	NDC:49483-280-00	100000 in 1 CARTON; Type 0: Not a Combination Product	12/17/2018	
3	NDC:49483-280-20	200 in 1 BOTTLE; Type 0: Not a Combination Product	09/15/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/17/2012	

Labeler - TIME CAP LABORATORIES, INC. (037052099)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
TIME CAP LABORATORIES, INC.		037052099	manufacture(49483-280)

Revised: 9/2023

TIME CAP LABORATORIES, INC.