SEVERE CONGESTION AND COUGH MAX- dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid
AptaPharma Inc.

Maximum strength Max Severe Congestion & Cough

Drug Facts

Active ingredients
(in each 20 mL)
Dextromethorphan HBr 20 mg
Guaifenesin 400 mg
Phenylephrine HCl 10 mg

Purpose

Dextromethorphan HBr	Cough suppressant
Guaifenesin	Expectorant
Phenylephrine	Nasal Decongestant

Uses
● helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes
● temporarily relieves these symptoms occurring with a cold:
  ● cough due to minor throat and bronchial irritation
  ● nasal congestion

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.
• For children under 12 years of age

Ask a doctor before use if you have ● heart disease ● thyroid disease ● high blood pressure ● diabetes
● trouble urinating due to an enlarged prostate gland ● cough that lasts or is chronic such as occurs with smoking,
asthma, chronic bronchitis or emphysema ● cough that occurs with too much phlegm (mucus)

When using this product ● do not use more than directed

Stop use and ask a doctor if
●nervousness, dizziness or sleeplessness occur ● symptoms do not get better within 7 days or are accompanied by a
fever ● cough 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.

Directions
- take only as recommended
- use dosage cup
- mL =milliliter
- do not take more than 6 doses in any 24-hour period

Age	Dose
Adults & children 12 years and older	20 mL every 4 hours
Children under 12 years of age	Do not use

Other information
- each 20 mL contains: sodium 10 mg
- dosage cup provided
- store between 15-30°C (59-86°F)
- do not refrigerate

Inactive ingredients
Anhydrous citric acid, edetate disodium, FD&C Blue # 1, FD&C Red # 40, flavors, glycerin, propylene glycol, propyl
gallate, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

Questions? Call weekdays from 9:30AM to 4:30 PM EST **1-877-798-5944**

Maximum Strength Max Severe Congestion & Cough

AP SAFE® NDC 76281-517-25

Compare to Mucinex® FAST-MAX™ Severe Congestion & Cough Active ingredients*

Maximum Strength
Max Severe Congestion & Cough

Dextromethorphan HBr/
Cough Suppressant
Guaifenesin /Expectorant
Phenylephrine HCl / Nasal Decongestant

Congestion& Cough

Relief of:
- **Cough**
- **Thins & Loosens Mucus**
- **Nasal & Chest Congestion**

Adults- For Ages 12 and over

6 FL OZ (177 mL)

DO NOT USE IF PRINTED SEAL UNDER CAP IS TORN OR MISSING

Manufactured by:
AptaPharma Inc.,
1533 Union Ave.
Pennsauken, NJ 08110

This product is not manufactured or distributed by Reckitt Benckiser Inc., distributor of Mucinex® FAST-MAX™ Severe
Congestion & Cough.

Front

PNL 4

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 right away.

Directions

- take only as recommended
- use dosage cup
- mL = milliliter
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- do not refrigerate

PNL 1

Peel Corner to Read Complete Drug Facts and Information

DO NOT USE IF PRINTED SEAL UNDER CAP IS TORN OR MISSING

Manufactured by:
AplaPharma Inc.,
1533 Union Ave.
Pennsauken, NJ 08110
AP-LB-002

3 76281 51725 5

Lot: Exp:

1.375 1.500
2.875

PNL 2

Drug Facts

Active ingredients (in each 20 mL) — **Purpose**

Dextromethorphan HBr 20 mg..... Cough suppressant
Guaifenesin 400 mg..... Expectorant
Phenylephrine HCl 10 mg..... Nasal Decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes
- temporarily relieves these symptoms occurring with a cold:
  - cough due to minor throat and bronchial irritation
  - nasal congestion

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.

PNL 3

Drug Facts (continued)

- for children under 12 years of age

Ask a doctor before use if you have

- heart disease
- thyroid disease
- high blood pressure
- diabetes
- trouble urinating due to an enlarged prostate gland
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema.
- cough that occurs with too much phlegm (mucus)

When using this product

- **do not use more than directed**

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occur
- symptoms do not get better within 7 days or are accompanied by a fever
- cough comes back, or occurs with fever, rash or persistent headache. These could be signs of a serious condition.

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SEVERE CONGESTION AND COUGH MAX

dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76281-517
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	10 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	blue	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76281-517-25	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/30/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC Monograph Drug	M012	01/30/2024	

Labeler - AptaPharma Inc. (790523323)

Registrant - AptaPharma Inc. (790523323)

Establishment

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(76281-517)

Revised: 1/2024 AptaPharma Inc.