ADULT TUSSIN COUGH AND CHEST CONGESTION DM SUGAR FREEdextromethorphan hbr, guaifenesin liquid ATLANTIC BIOLOGICALS CORP.

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.

Drug Facts

Active ingredients (in each 10 mL)

Dextromethorphan HBr 20 mg
Guaifenesin 200 mg

Purposes

Cough suppressant

Expectorant

Uses

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes

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 that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema

Stop use and ask a doctor if

cough lasts more than 7 days, comes back, or is accompanied by 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

- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided
- keep dosing cup with product
- mL= milliliter
- this adult product is not intended for use in children under 12 years of age
- adults and children 12 years and over: 10 mL every 4 hours
- children under 12 years: do not use

Other information

- Phenylketonurics: contains Phenylalanine 30 mg per 10 mL
- store between 20-25°C(68-77°F). Do not refrigerate

Inactive ingredients

acesulfame potassium, citric acid, flavor cherry, glycerin, menthol crystals, purified water, sorbitol solution 70%, sodium citrate, sodium saccharin, sodium benzoate.

Questions or comments?

DISTRIBUTED BY:

ATLANTIC BIOLOGICALS CORP MIAMI, FL 33179

17856-1006-01

Tussin DM (Dextromethorphan / Guaifenesin) 10 MG / 100MG/ 5ML DELIVERS 5 ML



See package insert for indications and dosage schedule

Store at 20°-25°C (68°-77°F). Do Not refrigerate. ALCOHOL FREE / SUGAR FREE ** Keep this and all medication out of the reach of children**



17856-1006-01

Dosage 5 ML

Tussin Cough & Chest Congestion DM

GTIN: 00117856100614

S/N: 01893901

Exp: 05/15/23

Lot: 018939

Qty: 72 CUPS

Packaged by:Unit Dose Solutions Morrisville, NC 27560

Distributed by: AtlanticBiologicals Corp, Miarni FI 33179

Rev.08/21

Call to Reorder: 800.509.7592

17856-1006-02

Tussin DM

(Dextromethorphan /

Guaifenesin)

20 MG / 200 MG/ 10ML

DELIVERS 10ML

See package insert for indications and dosage schedule

Store at 20°-25°C (68°-77°F).Do Not refrigerate. ALCOHOL FREE / SUGAR FREE

** Keep this and all medication out of the reach of children**



17856-1006-02

Dosage 10 ML

Tussin Cough & Chest

Congestion DM

Qty: 72 CUPS

S/N

GTIN: 00117856100621

S/N: 01893701

Exp: 05/15/23

Lot: 018937



Packaged by:Unit Dose Solutions Morrisville, NC 27560

Distributed by: AtlanticBiologicals Corp, Miami Fl 33179

Rev.08/21

Call to Reorder: 800,509,7592

ADULT TUSSIN COUGH AND CHEST CONGESTION DM SUGAR FREE

dextromethorphan hbr, guaifenesin liquid

| Product Information | | | | |
|-------------------------|----------------|--------------------|--------------------------------|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:17856-1006(NDC:71399-1006) | |
| 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 10 mL |
|--|-------------------------------|--------------------|
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 200 mg in 10 mL |

| Inactive Ingredients | | | | |
|--|----------|--|--|--|
| Ingredient Name | Strength | | | |
| ACESULFAME POTASSIUM (UNII: 230V73Q5G9) | | | | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| MENTHOL (UNII: L7T10EIP3A) | | | | |
| WATER (UNII: 059QF0KO0R) | | | | |
| SORBITOL SOLUTION 70% (UNII: 8KW3E207O2) | | | | |
| SODIUM CITRATE (UNII: 1Q73Q2JULR) | | | | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | | | | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | | | | |

| Product Characteristics | | | | |
|-------------------------|-------------------|--------------|--|--|
| Color | white (colorless) | Score | | |
| Shape | | Size | | |
| Flavor | | Imprint Code | | |
| Contains | | | | |

| P | Packaging | | | | |
|---|----------------------|--|-------------------------|-----------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:17856- 1006-1 | 72 in 1 BOX, UNIT-DOSE | 11/17/2022 | | |
| 1 | NDC:17856- 1006-3 | 5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product | | | |
| 2 | NDC:17856- 1006-2 | 72 in 1 BOX, UNIT-DOSE | 11/17/2022 | | |
| 2 | NDC:17856- 1006-4 | 10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product | | | |

| Marketing Application N | | | |
|-------------------------|---------------------------------|-------------------------|-----------------------|
| Category | lumber or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC MONOGRAPH part341 | | 11/11/2022 | |

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

| Establishment | | | |
|---------------|---------|--------|---------------------|
| Name | Address | ID/FEI | Business Operations |

UNIT DOSE SOLUTIONS 360804194 repack(17856-1006)

Revised: 11/2022 ATLANTIC BIOLOGICALS CORP.