# MAXIMUM STRENGTH COUGH PLUS CHEST CONGESTION DMdextromethorphan hydrobromide and guaifenesin capsule, gelatin coated Spirit Pharmaceuticals LLC

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#### MAXIMUM STRENGTH COUGH+CHEST CONGESTION DM

# **Drug Facts**

| Active ingredients (in each softgel) | Purposes          |
|--------------------------------------|-------------------|
| Dextromethorphan HBr, USP 10 mg      | Cough suppressant |
| Guaifenesin, USP 200 mg              | 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.

#### **Directions**

- do not take more than 12 softgels in any 24-hour period
- this adult product is not intended for use in children under 12 years of age

| age                          | dose                     |
|------------------------------|--------------------------|
| adults and children 12 years | 2 softable overy 4 hours |

| and over                | 2 SUILYEIS EVELY 4 HUULS |
|-------------------------|--------------------------|
| children under 12 years | do not use               |

### Other information

- store at 20-25°C (68-77°F).
- avoid excessive heat above 40°C (104°F).

## **Inactive ingredients**

FD&C Red-40, gelatin, glycerin, polyethylene glycol 400, povidone K30, propylene glycol, purified water, special sorbitol, titanium dioxide

#### Questions or comments?

1-888-333-9792

DISTRIBUTED BY: SPIRIT PHARMACEUTICALS LLC

**RONKONKOMA, NY 11779** 

#### PRINCIPAL DISPLAY PANEL

VALUMEDS TM

Compare to the active ingredients in Robitussin® Maximum

Strength Cough+Chest Congestion DM\*

Maximum Strength

Cough + Chest Congestion DM

DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT GUAIFENESIN/ EXPECTORANT

MAXIMUM STRENGTH

#### Relieves

- cough
- mucus

10 SOFTGELS

Liquid Filled capsules



### MAXIMUM STRENGTH COUGH PLUS CHEST CONGESTION DM

dextromethorphan hydrobromide and quaifenesin capsule, gelatin coated

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:68210-4107 Route of Administration ORAL

| Active Ingredient/Active Moiety  |                                  |          |  |
|--|----------------------------------|----------|--|
| Ingredient Name  | Basis of Strength                | Strength |  |
| <b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN<br>HYDROBROMIDE | 10 mg    |  |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)                               | GUAIFENESIN                      | 200 mg   |  |

| Inactive Ingredients               |          |  |
|------------------------------------|----------|--|
| Ingredient Name                    | Strength |  |
| FD&C RED NO. 40 (UNII: WZB9127XOA) |          |  |
| GELATIN (UNII: 2G86QN327L)         |          |  |
| GLYCERIN (UNII: PDC6A3C0OX)        |          |  |

| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) |  |
|--|--|
| POVIDONE K30 (UNII: U725QWY32X)            |  |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)        |  |
| WATER (UNII: 059QF0KO0R)                   |  |
| SORBITOL (UNII: 506T60A25R)                |  |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)        |  |

| Product Characteristics |                 |              |          |  |
|-------------------------|-----------------|--------------|----------|--|
| Color                   | red (Light red) | Score        | no score |  |
| Shape                   | OVAL (Oblong)   | Size         | 20mm     |  |
| Flavor                  |                 | Imprint Code | 242;905  |  |
| Contains                |                 |              |          |  |

| P | Packaging            |   |                         |                       |
|---|----------------------|---|-------------------------|-----------------------|
| # | Item Code            | Package Description                                     | Marketing Start<br>Date | Marketing End<br>Date |
| 1 | NDC:68210-<br>4107-1 | 1 in 1 CARTON   | 07/30/2020              |                       |
| 1 |                      | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product |                         |                       |

| Marketing Information |   |                         |                       |
|-----------------------|---|-------------------------|-----------------------|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| OTC Monograph Drug    | M012  | 07/30/2020              |                       |
|                       |   |                         |                       |

# **Labeler -** Spirit Pharmaceuticals LLC (179621011)

Revised: 12/2023 Spirit Pharmaceuticals LLC