

COUGH SUPPRESSANT AND EXPECTORANT DM- tussin dm liquid

We Care Distributor 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.

Drug Facts

Active ingredients

Dextromethorphan HBr, USP 10 mg

Guaifenesin, USP 100 mg

Purpose

Cough suppressant

Expectorant

Uses

temporarily relieves cough due to minor throat and bronchial irritation as may occur with cold. It helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

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

- 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 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 the reach of children.

In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Directions

- Do not take more than 6 doses in a 24-hour period

- Repeat dose every 4 hours while symptoms last

| AGE | DOSE |
|---|--------------|
| adults and children 12 years of age and over | 10 mL |
| children 6 years to under 12 years of age | 5 mL |
| children 2 years to under 6 years of age | 2.5 mL |
| children under under 2 years of age | ask a doctor |

Other information

- Store at 15-30°C (59-86°F)
- Protect from freezing
- Alcohol free
- Protect from light
- Each teaspoon 5mL contains: Sodium 3 mg

Inactive ingredients

citric acid, dextrose**, flavor, FD&C red #40, glucose, glycerin, high fructose corn syrup, menthol, purified water, saccharin sodium, sodium benzoate

** contains one or more of these ingredients

Principal Display Panel

Compare to the Active Ingredients in Robitussin DM

Dextromethorphan HBr, 10 mg - guaifenesin, 100 mg

cough suppressant, expectorant

Non-Drowsy

Alcohol Free

Relieves- coughs, chest congestion and mucus

2 FL Oz (60 mL)

| <p>Drug Facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none"> Do not take more than 6 doses in a 24-hour period Repeat dose every 4 hours while symptoms last <table border="1"> <thead> <tr> <th>AGE</th> <th>DOSE</th> </tr> </thead> <tbody> <tr> <td>adults and children 12 years of age and over</td> <td>10 mL</td> </tr> <tr> <td>children 6 years to under 12 years of age</td> <td>5 mL</td> </tr> <tr> <td>children 2 years to under 6 years of age</td> <td>2.5 mL</td> </tr> <tr> <td>under 2 years of age</td> <td>ask a doctor</td> </tr> </tbody> </table> <p>Inactive ingredients citric acid, dextrose**, flavor FD&C red #40, glucose**, glycerin, high fructose corn syrup, menthol, purified water, saccharin sodium, sodium benzoate</p> <p>Other information</p> <ul style="list-style-type: none"> Store at 15-30°C (59-86°F) Protect from freezing Alcohol free Protect from light Each teaspoon 5mL contains: sodium 3mg <p>** contains one or more of these ingredients</p> | AGE | DOSE | adults and children 12 years of age and over | 10 mL | children 6 years to under 12 years of age | 5 mL | children 2 years to under 6 years of age | 2.5 mL | under 2 years of age | ask a doctor | <p>NDC: 70005-044-01</p>  <p>TUSSIN DM</p> <p>COMPARE TO ACTIVE INGREDIENTS IN Robitussin DM®*</p> <p>Cough Suppressant / Expectorant</p> <p>Controls Cough For Adults & Children</p> <ul style="list-style-type: none"> Alcohol Free Cough Formula Helps Loosen Phlegm (Mucus) & Relieve Chest Congestion <p><small>*This product is not manufactured or distributed by Whitehall - Robins Healthcare distributors of Robitussin DM®</small></p> <p>2 FL OZ (60 mL)</p> | <p>NDC: 70005-044-01</p>  <p>TUSSIN DM</p> <p>COMPARE TO ACTIVE INGREDIENTS IN Robitussin DM®*</p> <p>Cough Suppressant / Expectorant</p> <p>Controls Cough For Adults & Children</p> <ul style="list-style-type: none"> Alcohol Free Cough Formula Helps Loosen Phlegm (Mucus) & Relieve Chest Congestion <p><small>*This product is not manufactured or distributed by Whitehall - Robins Healthcare distributors of Robitussin DM®</small></p> <p>2 FL OZ (60 mL)</p> | <p>TAMPER EVIDENT: Do not use this product if printed inner cap seal is broken or missing.</p> <p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Guaifenesin USP 100 mg</td> <td>Expectorant</td> </tr> <tr> <td>Dextromethorphan HBr USP 10mg</td> <td>Cough Suppressant</td> </tr> </tbody> </table> <p>Uses temporarily relieves cough due to minor throat and bronchial irritation as may occur with cold. It helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive</p> <p>Warnings Do not use if you are now taking a prescription monamine 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 MAOI, ask a doctor or a pharmacist before taking this product.</p> <p>Ask a doctor before use if</p> <ul style="list-style-type: none"> cough that occurs with too much phlegm (mucus) cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema <p>Stop use and ask doctor if</p> <ul style="list-style-type: none"> 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. <p>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. ▶</p> | Active ingredients | Purpose | Guaifenesin USP 100 mg | Expectorant | Dextromethorphan HBr USP 10mg | Cough Suppressant |
|---|-------------------|------|--|-------|---|------|--|--------|----------------------|--------------|---|---|--|--------------------|---------|------------------------|-------------|-------------------------------|-------------------|
| AGE | DOSE | | | | | | | | | | | | | | | | | | |
| adults and children 12 years of age and over | 10 mL | | | | | | | | | | | | | | | | | | |
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| children 2 years to under 6 years of age | 2.5 mL | | | | | | | | | | | | | | | | | | |
| under 2 years of age | ask a doctor | | | | | | | | | | | | | | | | | | |
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| Guaifenesin USP 100 mg | Expectorant | | | | | | | | | | | | | | | | | | |
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COUGH SUPPRESSANT AND EXPECTORANT DM

tussin dm liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70005-044 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------------------|----------------|
| Dextromethorphan Hydrobromide (UNII: 9D2RT9KYH) (Dextromethorphan - UNII:7355X3ROTS) | Dextromethorphan Hydrobromide | 10 mg in 5 mL |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 100 mg in 5 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |

| | |
|---|--|
| DEXTROSE (UNII: IY9XDZ35W2) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S) | |
| MENTHOL (UNII: L7T10EIP3A) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |

Product Characteristics

| | | | |
|----------|-----------------|--------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | CHERRY (Cherry) | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70005-044-01 | 1 in 1 CARTON | 06/29/2016 | |
| 1 | | 60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | 06/29/2016 | |

Labeler - We Care Distributor Inc. (079832998)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------|---------|-----------|------------------------|
| PURINE PHARMA LLC | | 019950491 | manufacture(70005-044) |

Revised: 8/2016

We Care Distributor Inc.