DRKIDS CHILDRENS COUGH AND CHEST CONGESTION DM- dextromethorphan hydrobromide, guaifenesin solution CalmCo LLC

DrKids Children's Cough & Chest Congestion DM

Active Ingredient (in each 5mL)

Dextromethorphan HBr, USP, 5mg Guaifenesin, USP, 100mg

Purpose

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 make cough more productive

Warnings

Do not use

if your child is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for two weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Ask a doctor before use if your child has

persistent or chronic cough such as occurs with asthma or if cough is accompanied by excessive phlegm (mucus).

Stop use and ask a doctor if

cough lasts for more than 7 days, tends to recur, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition.

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 give more than 6 doses in any 24 hour period give the recommended number of vials below, following the instructions under How to Open and Use on the side panel empty all liquid in each Single-Use Vial when dosing

Dosing Chart

| Age (Years) | Dose |
|---------------------------------------|--|
| under 4 years | Consult a doctor |
| 4 – 5 years | 1 Single-Use Vial (5 mL) every 4 hours |
| 6 - 11 years | 1 - 2 Single-Use Vials (5 mL each) every 4 hours |
| Adults and children 12 years and over | 2 – 4 Single-Use Vials (5 mL each) every 4 hours |

Inactive Ingredients

citric acid, glycerin, mixed berry flavor, propylene glycol, purified water, sodium benzoate, sodium saccharin, sorbitol, sucralose, trisodium citrate dihydrate, xanthan gum

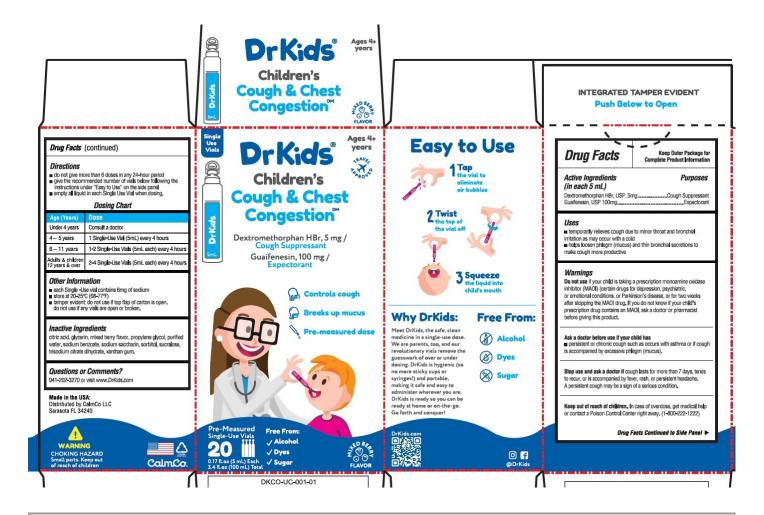
Other information

- each Single-Use vial contains 6mg of sodium
- store at 20-25°C (68-77°F)
- tamper evident: do not use if top flap of carton is open. Do not use if any vials are open or broken

Ouestions or comments?

941-202-3270 or visit www.DrKids.com

Package



DRKIDS CHILDRENS COUGH AND CHEST CONGESTION DM

dextromethorphan hydrobromide, guaifenesin solution

| Product Information | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:73282-0013 |
| Route of Administration | ORAL | | |

| Active Ingredient/Active Moiety | | | | |
|--|----------------------------------|-------------------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| | DEXTROMETHORPHAN HYDROBROMIDE | 5 mg in 5 mL | | |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 100 mg in 5 mL | | |

| Inactive Ingredients | |
|--|----------|
| Ingredient Name | Strength |
| WATER (UNII: 059QF0KO0R) | |
| TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K) | |
| SORBITOL (UNII: 506T60A25R) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |

| XANTHAN GUM (UNII: TTV12P4NEE) | |
|-------------------------------------|--|
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |

| Product Characteristics | | | |
|-------------------------|-------|--------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | BERRY | Imprint Code | |
| Contains | | | |

| P | Packaging | | | |
|---|----------------------|---|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:73282- 0013-1 | 20 in 1 CARTON | 12/15/2023 | |
| 1 | | 5 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug | M012 | 12/15/2023 | 10/31/2025 |
| | | | |

Labeler - CalmCo LLC (079308308)

Revised: 5/2024 CalmCo LLC