COUGH DM- dextromethorphan polistirex suspension, extended release Praxis, LLC

Walgreen Co. Cough DM Drug Facts

Active ingredient (in each 5 mL)

Dextromethorphan polistirex equivalent to 30 mg dextromethorphan hydrobromide

Purpose

Cough suppressant

Uses

temporarily relieves

- cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
- the impulse to cough to help you get to sleep

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.

Allergy Alert:Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions.

Ask a doctor before use if you have

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

Stop use and ask a doctor if

- side effects occur. You may report side effects to FDA at 1-800-FDA-1088.
- cough lasts more than 7 days, cough comes back, or occurs with fever, rash or headache that lasts. 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-

Directions

- shake bottle well before use
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor

| adults and children 12 | 10 mL every 12 hours, |
|-----------------------------|--------------------------------|
| years of age | not to exceed 20 mL in 24 |
| and over | hours |
| children 6 to under 12 | 5 mL every 12 hours, |
| years of age | not to exceed 10 mL in 24 |
| | hours |
| children 4 to under 6 years | 2.5 mL every 12 hours, |
| of age | not to exceed 5 mL in 24 hours |
| children under 4 years of | do not use |
| age | |

Other information

- each 5 mL contains: sodium 5 mg
- store at 20° to 25°C (68° to 77°F)
- dosing cup provided

Inactive ingredients

artificial grape flavor, D&C Red #30 aluminum lake, FD&C Blue #1 aluminum lake, glycerin, high fructose corn syrup, methylparaben, polysorbate 80, polyvinyl acetate, povidone, propylparaben, purified water, sodium metabisulfite, sodium polystyrene sulfonate, sucrose, tartaric acid, tragacanth gum, triacetin, xanthan gum

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

VALUE SIZE

Walgreens

WALGREENS PHARMACIST RECOMMENDED

Compare to the active ingredient in Delsym ®

12-HOUR COUGH RELIEF

Cough DM

DEXTROMETHORPHAN POLISTIREX EXTENDED-RELEASE ORAL SUSPENSION / COUGH SUPPRESSANT

12 Hour

Day or Night

- Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions
- Alcohol free

Dosing cup included

- 5 FL OZ (148 mL)
- Grape flavored liquid



| Produ Route Route Activ DEXTR DEXTR Inact FD&C GLYCE HIGH I METHY POLYS POLYS POLYS POLYS POLYS POLYS POLYS SODIU SODIU SUCRO | ROMETHORPH ROMETHORPH ELUE NO. 1 ERIN (UNII: PE FRUCTOSE C YLPARABEN SORBATE 80 | stration ent/Active I Ingrec HAN HYDROBE AN - UNII:7355X3 dients (UNII: H3R47K3 | dient Name ROMIDE (UNII: 9D2RTI9 BROTS) Ingredient Nam TBD) | (үн) | | | S68-260 Strength 30 mg in 5 mL trength |
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| POLYS POLYV POVID PROPY WATE SODIU SODIU SUCRO | SORBATE 80 | (UNII: A2I8C7HI9 | JNII: XY6UN3QB6S) | | | | |
| POLYV POVID PROPY WATE SODIU SODIU SUCRO | | | ЭТ) | | | | |
| POVID PROPY WATE SODIU SODIU SUCRO | VINYI ACETA | (UNII: 60ZP39Z | ZG8H) | | | | |
| PROPY WATE SODIU SODIU SUCRO | | TE (UNII: 32K49 | 97ZK2U) | | | | |
| WATE SODIU SODIU SUCRO | ONE, UNSPE | CIFIED (UNII: F | Z989GH94E) | | | | |
| SODIU SODIU SUCRO | YLPARABEN | (UNII: Z8IX2SC1 | OH) | | | | |
| SODIU SUCRO | R (UNII: 059Q | F0KO0R) | | | | | |
| SUCRO | JM METABIS | ULFITE (UNII: 4) | VON5FNS3C) | | | | |
| | JM POLYSTY | RENE SULFON | ATE (UNII: 1699G8679Z |) | | | |
| тлртл | OSE (UNII: C1 | 51H8M554) | | | | | |
| IANIA | ARIC ACID (U | NII: W4888I119H | 1) | | | | |
| TRAGA | ACANTH (UNI | l: 2944357020) | | | | | |
| TRIACETIN (UNII: XHX3C3X673) | | | | | | | |
| XANTHAN GUM (UNII: TTV12P4NEE) | | | | | | | |
| D&C R | RED NO. 30 (| UNII: 2S42T2808 | 8B) | | | | |
| Prod | luct Chara | acteristics | | | | | |
| Color | | | purple | Score | | | |
| Shape | | | | Size | | | |
| Flavo | | | | | | | |
| Conta | | | | Imprint Code | | | |
| Conta | 21115 | | | | | | |
| Pack | aging | | | | | | |
| # Ite | _ | Pac | ckage Description | | Marketing S Date | | eting End Date |
| 1 NDC | em Code | | | | 07/01/2015 | 08/01/202 | 22 |

| AN | IDA | ANDA091135 | 07/01/2015 | | |
|-----------------------|-----------------------|---|-------------------------|-----------------------|--|
| | Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| Marketing Information | | | | | |
| | | | | | |
| 2 | | 148 mL in 1 BOTTLE; Type 0: Not a Combination Product | | | |
| 2 | NDC:59368-260- 01 | 1 in 1 CARTON | 05/20/2017 | | |
| 1 | | 89 mL in 1 BOTTLE; Type 0: Not a Combination Product | | | |

Labeler - Praxis, LLC (016329513)

| Establishment | | | |
|---------------|---------|-----------|---|
| Name | Address | ID/FEI | Business Operations |
| Praxis, LLC | | 016329513 | label(59368-260), pack(59368-260), manufacture(59368-260) |

Revised: 1/2023

Praxis, LLC