

EQUALINE COUGH DM- dextromethorphan polistirex suspension
Supervalu Inc

SuperValu Inc. 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 (1-800-222-1222).

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 doctor
- mL = milliliter

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

Other information

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

Inactive Ingredients

D&C Red #30 aluminum lake, D&C Yellow #10 aluminum lake, flavor, 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?

1-877-932-7948

Package/Label Principal Display Panel

compare to Delsym® active ingredient

cough DM

dextromethorphan polistirex extended-release oral suspension

(cough suppressant)

day or night

12 hour cough relief

CONTAINS SODIUM METABISULFITE, A SULFITE THAT MAY CAUSE ALLERGIC-TYPE REACTIONS

orange-flavored liquid

dosing cup included

ALCOHOL-FREE

3 FL OZ (89mL)



| EQUALINE COUGH DM | | | |
|--|--|----------------------------------|------------------|
| dextromethorphan polistirex suspension | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:41163-384 |
| Route of Administration | ORAL | | |
| Active Ingredient/Active Moiety | | | |
| | Ingredient Name | Basis of Strength | Strength |
| | DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9 KYH) (DEXTROMETHORPHAN - UNII: 7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 30 mg in 5 mL |
| Inactive Ingredients | | | |
| | Ingredient Name | | Strength |

| |
|--|
| POLISTIREX (UNII: 5H9W9GTW27) |
| D&C RED NO. 30 (UNII: 2S42T2808B) |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) |
| GLYCERIN (UNII: PDC6A3C0OX) |
| HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S) |
| METHYL PARABEN (UNII: A2I8C7HI9T) |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) |
| POLYVINYL ACETATE (UNII: 32K497ZK2U) |
| POVIDONES (UNII: FZ989GH94E) |
| PROPYL PARABEN (UNII: Z8IX2SC1OH) |
| WATER (UNII: 059QF0KO0R) |
| SODIUM METABISULFITE (UNII: 4VON5FNS3C) |
| SODIUM POLYSTYRENE SULFONATE (UNII: 1699G8679Z) |
| SUCROSE (UNII: C151H8M554) |
| TARTARIC ACID (UNII: W4888I119H) |
| TRAGACANTH (UNII: 2944357O2O) |
| TRIACETIN (UNII: XHX3C3X673) |
| XANTHAN GUM (UNII: TTV12P4NEE) |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|--|
| Color | ORANGE | Score | |
| Shape | | Size | |
| Flavor | ORANGE | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:41163-384-21 | 1 in 1 CARTON | 10/19/2012 | |
| 1 | | 89 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA091135 | 10/19/2012 | |

Labeler - Supervalu Inc (006961411)