TUSSIN NIGHTTIME COUGH DM MAXIMUM STRENGTH- dextromethorphan hbr, doxylamine succinate liquid Family Dollar (FAMILY WELLNESS)

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 (in each 10 mL)

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 mg

Purposes

Cough suppressant

Antihistamine

Uses

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
 - runny nose
 - sneezing
 - itchy, watery eyes
 - itching of the nose or throat
- controls the impulse to cough to help you sleep

Warnings

Do not use

- to sedate a child or to make a child sleepy
- 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

- glaucoma
- trouble urinating due to an enlarged prostate gland
- a cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma,

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

- do not use more than directed
- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur especially in children

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 (1-800-222-1222) right away.

Directions

- this adult product is not intended for use in children under 12 years of age
- do not take more than 4 doses in any 24-hour period
- measure only with dosing cup provided. Do not use any other dosing device.
- keep dosing cup with product
- mL = milliliter
- adults and children 12 years and over: 10 mL every 6 hours
- children under 12 years: do not use

Other information

• store between 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

anhydrous citric acid, FD&C red #40, flavors glycerin, high fructose corn syrup, menthol, polyethylene glycol 300, propylene glycol, purified water, sodium benzoate, sodium citrate, sucralose, xanthan gum

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

COMPARE TO THE ACTIVE INGREDIENTS IN ROBITUSSIN® MAXIMUM STRENGTH NIGHTTIME COUGH DM*

Adult

For Ages 12 Years & Over

MAXIMUM STRENGTH

Tussin Nighttime Cough DM

Dextromethorphan HBr

Doxylamine Succinate

Cough Suppressant

Antihistamine

Relieves:

- Cough
- Itchy throat
- Runny nose

NIGHTTIME

Alcohol-Free

Dosage cup provided

FL OZ (mL)

*This product is not manufactured or distributed by Pfizer Consumer Healthcare, distributors of Robitussin® Maximum Strength Nighttime Cough DM.

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY: MIDWOOD BRANDS, LLC

10611 MONROE RD., MATTHEWS, NC 28105

Package Label



FAMILY WELLNESS Maximum Strength Tussin Nighttime Cough DM

TUSSIN NIGHTTIME COUGH DM MAXIMUM STRENGTH

dextromethorphan hbr, doxylamine succinate liquid

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:55319-414 Route of Administration ORAL

| Active Ingredient/Active Moiety | | | | | |
|--|----------------------------------|---------------------|--|--|--|
| Ingredient Name | Basis of Strength | Strength | | | |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 30 mg in 10 mL | | | |
| DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL) | DOXYLAMINE SUCCINATE | 12.5 mg in 10 mL | | | |

| Inactive Ingredients | | | |
|--|----------|--|--|
| Ingredient Name | Strength | | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | | | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | |
| HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S) | | | |
| MENTHOL (UNII: L7T10EIP3A) | | | |
| POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ) | | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | | |
| WATER (UNII: 059QF0KO0R) | | | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | | | |
| TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K) | | | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | | | |
| XANTHAN GUM (UNII: TTV12P4NEE) | | | |

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

| F | Packaging | | | | | | | |
|---|----------------------|---|-------------------------|-----------------------|--|--|--|--|
| # | tem Code | Package Description | Marketing Start Date | Marketing End Date | | | | |
| 1 | NDC:55319-414- 04 | 1 in 1 BOX | 07/31/2016 | 10/25/2024 | | | | |
| 1 | _ | 118 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 | | |
| OTC monograph final | part341 | 07/31/2016 | 10/25/2024 | | |
| | | | | | |

Labeler - Family Dollar (FAMILY WELLNESS) (024472631)

Revised: 10/2021 Family Dollar (FAMILY WELLNESS)