# 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.

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#### **Drug Facts**

## Active ingredients (in each 20 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: 20 mL every 6 hours
- children under 12 years: do not use

#### Other information

- each 20 mL contains: sodium 9 mg
- store between 20-25°C (68-77°F). Do not refrigerate.

## **Inactive ingredients**

anhydrous citric acid, carboxymethylcellulose sodium, FD&C blue #1, FD&C red #40, flavors, glycerin, high fructose corn syrup, menthol, polyethylene glycol, 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 PRINTED SAFETY SEAL 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:55319-801
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 20 mL		
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 20 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, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
XANTHAN GUM (UNII: TTV12P4NEE)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)			

Product Characteristics			
Color	red	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:55319-801- 04	1 in 1 BOX	12/31/2018	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	12/31/2018	10/25/2024	

## Labeler - Family Dollar (FAMILY WELLNESS) (024472631)