

**ADULT AUROTUSSIN MAXIMUM STRENGTH NIGHTTIME COUGH DM -  
dextromethorphan hbr, doxylamine succinate liquid  
Aurohealth LLC**

*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 10 mL)**

Dextromethorphan HBr, USP 30 mg  
Doxylamine Succinate, USP 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**

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

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

**Directions**

- measure only with dosing cup provided
- keep dosing cup with product
- mL = milliliter
- do not take more than 4 doses (8 tsp) in any 24-hour period
- this adult product is not intended for use in children under 12 years of age
- shake well before using

<b>age</b>	<b>dose</b>
adults and children 12 years and over	10 mL every 6 hours
children under 12 years	do not use

**Other information**

- **each 10 mL contains:** sodium 7 mg
- store at 20-25°C (68-77°F)
- alcohol-free

**Inactive ingredients**

anhydrous citric acid, 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**

**1-855-274-4122**

**Distributed by:**

Aurohealth LLC.  
2572 Brunswick Pike,  
Lawrenceville, NJ 08648

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 4 FL OZ (118 mL Bottle)**

**AUROHEALTH**

**NDC 58602-159-24**

**Compare to the active ingredients in  
Adult Robitussin® Maximum Strength  
Nighttime Cough DM\***

**ADULT**

**Aurotussin**

**MAXIMUM STRENGTH**

**Nighttime Cough DM**

**Each 10 mL dose of oral solution contains:**

**30 mg - Dextromethorphan HBr, USP (Cough Suppressant)**

**12.5 mg - Doxylamine Succinate, USP (Antihistamine)**

**Relieves:**

**Cough**

**Itchy Throat**

**Runny Nose**

**Max Strength Nighttime Cough Control**

**DM**

**NIGHTTIME**

**MAX**

**Pineapple Flavor  
For Ages 12 & Over**

**4 FL OZ  
(118 mL)**



# ADULT AUROTUSSIN MAXIMUM STRENGTH NIGHTTIME COUGH DM

dextromethorphan hbr, doxylamine succinate liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58602-159
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>ORANGE</b> (UNII: 5EVU04N5QU)	
<b>PINEAPPLE</b> (UNII: 2A88ZO081O)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HIGH FRUCTOSE CORN SYRUP</b> (UNII: XY6UN3QB6S)	
<b>LEVOMENTHOL</b> (UNII: BZ1R15MTK7)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	RED (a clear red colored liquid)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MENTHOL, ORANGE, PINEAPPLE	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-159-24	1 in 1 CARTON	05/02/2016	
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	05/02/2016	

**Labeler** - Aurohealth LLC (078728447)

### Establishment

Name	Address	ID/FEI	Business Operations
Aurohealth LLC		078728447	MANUFACTURE(58602-159)

