

**NIGHTTIME COUGH DM- dextromethorphan hbr, doxylamine succinate solution**  
**L.N.K. International, Inc.**

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**Quality Plus 44-043**

***Active ingredients (in each 20 mL)***

Dextromethorphan HBr 30 mg  
Doxylamine succinate 12.5 mg

***Purpose***

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:
  - itching of the nose or throat
  - sneezing
  - itchy, watery eyes
  - runny nose
- controls the impulse to cough to help you 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.

**Ask a doctor before use if you have**

- a cough that occurs with too much phlegm (mucus)
- glaucoma
- difficulty in urination due to enlargement of the prostate gland
- a breathing problem or persistent or chronic cough 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**

- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- use caution when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

**Stop use and ask a doctor if**

cough persists more than 7 days, tends to recur, or is accompanied by a 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.

**Directions**

- **do not take more than directed**
- do not take more than 4 doses in any 24-hour period
- mL = milliliter
- only use the dose cup provided
- adults and children 12 years and over: 20 mL in dosing cup provided every 6 hours
- children under 12 years: do not use

**Other information**

- **each 20 mL contains:** sodium 14 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

**Inactive ingredients**

anhydrous citric acid, FD&C blue #1, FD&C red #40, flavors, glycerin, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium chloride, sodium citrate dihydrate, sucralose, sugar, xanthan gum

**Questions or comments?**

**1-800-426-9391**

**Principal display panel**

NDC 50844-043-36

**Quality**

## **+Plus**

Compare to the active ingredients  
in Robitussin® MAXIMUM STRENGTH  
Nighttime Cough DM\*

MAXIMUM STRENGTH

## **NIGHTTIME COUGH DM**

DEXTROMETHORPHAN HBr  
Cough suppressant  
DOXYLAMINE SUCCINATE  
Antihistamine

- Controls cough
- Relieves runny  
nose & sneezing

Menthol-Berry  
Flavor

Ages 12 Years and Over

Dosage cup  
included

**4 FL OZ (118 mL)**

**TAMPER EVIDENT: DO NOT USE IF PRINTED  
NECK WRAP IS BROKEN OR MISSING**

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED  
SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

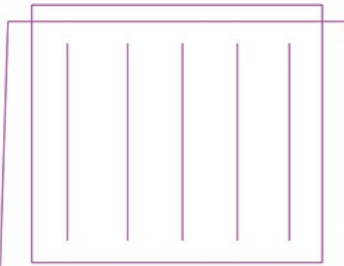
\*This product is not manufactured or distributed by  
GlaxoSmithKline Consumer Healthcare Holdings (US) LLC,  
owner of the registered trademark Robitussin® MAXIMUM  
STRENGTH Nighttime Cough DM.

50844      REV0123A04336

Distributed by  
**LNK INTERNATIONAL, INC.**  
60 Arkay Drive  
Hauppauge, NY 11788  
USA

## **PARENTS:**

Learn about teen medicine abuse  
[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)



KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

**Drug Facts**

Active ingredients (in each 20 mL)	Purpose
Dextromethorphan HBr 30 mg...Cough suppressant Doxylamine succinate 12.5 mg.....Antihistamine	

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**Drug Facts (continued)**

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50844 REV0123A04336

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B-1603-043-36  
REV0123A04336

QUALITY PLUS

MAXIMUM STRENGTH

NIGHTTIME Cough DM

4 FL OZ (118 mL)

QUALITY PLUS

NDC 50844-043-36

Compare to the active ingredients in Robitussin® MAXIMUM STRENGTH Nighttime Cough DM\*

MAXIMUM STRENGTH

NIGHTTIME Cough DM

DEXTROMETHORPHAN HBr  
Cough suppressant  
DOXYLAMINE SUCCINATE  
Antihistamine



- Controls cough
- Relieves runny nose & sneezing

Menthol-Berry Flavor

Ages 12 Years and Over



Dosage cup included

4 FL OZ (118 mL)

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No Print / No Varnish  
Lot no. & Exp. date

Quality Plus 44-043

**NIGHTTIME COUGH DM**

dextromethorphan hbr, doxylamine succinate solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50844-043
<b>Route of Administration</b>	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: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 20 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HIGH FRUCTOSE CORN SYRUP</b> (UNII: XY6UN3QB6S)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

## Product Characteristics

<b>Color</b>	red (maroon)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY, MENTHOL	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50844-043-36	1 in 1 CARTON	07/16/2021	
1		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/16/2021	

**Labeler** - L.N.K. International, Inc. (038154464)

## **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		967626305	manufacture(50844-043) , pack(50844-043)

Revised: 5/2024

L.N.K. International, Inc.