TUSSIN DM- dextromethorphan hbr, guaifenesin solution Cardinal Health 110, LLC. DBA Leader

Leader 44-030

Active ingredients (in each 20 mL)

Dextromethorphan HBr 20 mg Guaifenesin 400 mg

Purpose

Cough suppressant Expectorant

Uses

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes

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

- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

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 6 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 4 hours
- children under 12 years: do not use

Other information

- each 20 mL contains: sodium 16 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, microcrystalline cellulose, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium chloride, sodium citrate dihydrate, sorbitol, sucralose, xanthan gum

Questions or comments?

1-800-426-9391

Principal Display Panel

LEADER♥™

NDC 70000-0628-2

Maximum Strength

Tussin DM Cough & Chest Congestion DM

Dextromethorphan HBr Guaifenesin

Cough Suppressant Expectorant

Menthol-Berry Flavor

Ages 12 Years and Over

Controls Cough Relieves Chest Congestion Thins & Loosens Mucus

COMPARE TO
ROBITUSSIN®
MAXIMUM STRENGTH
COUGH + CHEST
CONGESTION dm
active ingredients*

100% Money Back Guarantee

8 FL OZ (237 mL)

*This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, owner of the registered trademark Robitussin® Maximum Strength Cough + Chest Congestion DM. 50844 ORG012303019

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√All LEADER™ Brand Products Have A

100% Money Back Guarantee

Return to place of purchase if not satisfied.

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

CLOSE TIGHTLY TO OPEN PUSH DOWN & TURN

PARENTS:

Learn about teen medicine abuse www.StopMedicineAbuse.org



TUSSIN DM

dextromethorphan hbr, guaifenesin solution

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:70000-0628 Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERIN (UNII: PDC6A3C0OX)		
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3MJQ0SDW1A)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)		
SORBITOL (UNII: 506T60A25R)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		
XANTHAN GUM (UNII: TTV12P4NEE)		

Product Characteristics			
Color	red	Score	
Shape		Size	
Flavor	MENTHOL, BERRY	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000- 0628-2	1 in 1 CARTON	03/16/2023	
1		237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:70000- 0628-1	1 in 1 CARTON	03/16/2023	
2		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	03/16/2023	

Labeler - Cardinal Health 110, LLC. DBA Leader (063997360)

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		967626305	manufacture(70000-0628) , pack(70000-0628)	

Revised: 7/2023 Cardinal Health 110, LLC. DBA Leader