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

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.

Cardinal Health Tussin DM Drug Facts

Active ingredients (in each 10 mL)

Dextromethorphan HBr, USP 20 mg Guaifenesin, USP 200 mg

Purposes

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)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema

Stop use and ask a doctor if

cough lasts for more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign 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

- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided
- keep dosing cup with product
- mL = milliliter
- · this adult product is not intended for use in children under 12 years of age

age	dose	
adults and children 12 years and over	10 mL every 4 hours	
children under 12 years	do not use	

Other information

- each 10 mL contains: sodium 6 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

anhydrous citric acid, FD&C red no. 40, flavor, glycerin, high fructose corn syrup, menthol, propylene glycol, purified water, sodium benzoate, sodium citrate, sucralose

Questions or comments?

1-800-719-9260

Principal Display Panel

Adult Tussin DM

Cough + Chest Congestion DM

Dextromethorphan HBr

Guaifenesin

Cough Suppressant

Expectorant

Ages 12 Years and Over

Relieves:

COUGH

MUCUS

COMPARE TO ROBITUSSIN® COUGH + CHEST CONGESTION DM active ingredients

Non-Drowsy

100% Money Back Guarantee

8 FL OZ (237mL)



LEADER TUSSIN DM

dextromethorphan hbr, guaifenesin solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0319
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 10 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 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)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)			
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			

Product Characteristics			
Color	RED (clear)	Score	
Shape		Size	
Flavor	CHERRY (Fruity)	Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:70000- 0319-1	1 in 1 CARTON	11/01/2017		
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:70000- 0319-2	1 in 1 CARTON	11/01/2017		
2		237 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	11/01/2017	

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

Revised: 6/2021 Cardinal Health 110, LLC. dba Leader