TUSSIN COUGH DM SUGAR FREE- dextromethorphan hbr, guaifenesin liquid P & L Development, 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.

Drug Facts

Active ingredients (in each 10 mL)

Dextromethorphan HBr 20 mg
Guaifenesin 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 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

- do not take more than 6 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
- this adults product is not intended for use in children under 12 years of age
- adults and children 12 years and over: 10 mL every 4 hours
- children under 12 years: do not use

Other information

• store between 20-25°C (68-77°). Do not refrigerate.

Inactive ingredients

acesulfame potassium, citric acid, flavors, glycerin, methylparaben, polyethylene glycol, povidone, propylene glycol, purified water, saccharin sodium, sodium benzoate

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to the active ingredients in Robitussin® Peak Cold Sugar-Free Cough + Chest Congestion DM*

adult

TUSSIN dm

sugar-free

cough & chest Congestion

Dextromethorphan HBr

Guaifenesin

Relieves:

- Cough
- Mucus

for ages 12 years & over

alcohol-free

non-drowsy

specially formulated for diabetics

FL OZ (mL)

Dosing Cup Included

*This product is not manufactured or distributed by Pfizer Consumer Healthcare, distributors of Robitussin® Peak Cold Sugar-Free Cough+Chest Congestion DM.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING.

Manufactured by:

PL Developments

11865 S. Almaneda St

Lynwood, CA 90262

Package Label

Drug Facts (continued)

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Compare to the active ingredients in Robitussin[®] Peak Cold Sugar-Free Cough+Chest Congestion DM*

NDC 49580-0817-4



relieves:

- · cough
- chest congestion

for ages 12 years & over alcohol-free non-drowsy

4 fl oz (118 mL)

specially formulated for diabetics



Compare to the active ingredients in Robitussin® Peak Cold Sugar-Free Cough+Chest Congestion DM*

NDC 49580-0817-4

adult tussin dm sugar-free cough & chest congestion

relieves:

- · cough
- chest congestion

for ages 12 years & over alcohol-free non-drowsy

4 fl oz (118 mL)

specially formulated for diabetics

Drug Facts

Active ingredients

Purposes

(in each 10 mL)

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Expectorant

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helps loosen phlegm (mucus) and thin bronchial
secretions to drain bronchial tubes

Warnings
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monoamine oxidase inhibitor (MAOI) (certain drugs for
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PLD-J324C FC005270

Let No.: Exp. Date:

READYinCASE Adult Sugar-Free Tussin DM

TUSSIN COUGH DM SUGAR FREE

dextromethorphan hbr, quaifenesin liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:49580-0817

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
(DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 10 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL

Inactive Ingredients				
Ingredient Name	Strength			
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
GLYCERIN (UNII: PDC6A3C0OX)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POVIDONE (UNII: FZ 989GH94E)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				

F	Packaging						
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:49580- 0817-4	1 in 1 BOX	08/31/2018	08/31/2025			
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 final	part341	08/31/2018	08/31/2025	

Labeler - P & L Development, LLC (101896231)

Revised: 6/2023 P & L Development, LLC