ADULT TUSSIN COUGH AND CHEST CONGESTION DM- dextromethorphan hbr, guaifenes in liquid

Freds Inc

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 the dosing cup provided. Do not use any other dosing device.
- keep dosing cup with product
- mL= milliliter
- this adult 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°F). Do not refrigerate

Inactive ingredients

anhydrous citric acid, FD&C red 40, flavor, glucose, glycerin, high fructose corn syrup, menthol, 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 Pobitussin® Peak Cold Cpough-+Chest Congestion DM*

Adult

Tussin Cough + Chest Congestion DM

DEXTROMETHORPHAN HBr 20 mg (Cough Suppressant)

GUAIFENESIN 200 mg (Expectorant)

Relieves:

- Cough
- Mucus

NON-DROWSY

ALCOHOL-FREE

FL OZ (mL)

DOSAGE CUP INCLUDED

FOR AGES 12 & OVER

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

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

DISTRIBUTED BY: fred's, Inc.

4300 NEW GETWELL RD,

MEMPHIS, TN 38118

www.fredsinc.com

Package Label



FRED'S PHARMACY Adult Tussin Cough + Chest Congestion DM

ADULT TUSSIN COUGH AND CHEST CONGESTION DM

dextromethorphan hbr, guaifenesin liquid

Product Information	oduct Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-385		
Route of Administration	ORAL				

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DEXTRO METHO RPHAN HYDRO BRO MIDE (UNII: 9 D2RTI9 KYH) (DEXTRO METHO RPHAN - 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	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
DEXTROSE (UNII: IY9 XDZ35W2)		
GLYCERIN (UNII: PDC6A3C0OX)		
HIGH FRUCTO SE CORN SYRUP (UNII: XY6 UN3QB6S)		
MENTHOL (UNII: L7T10EIP3A)		
WATER (UNII: 059QF0KO0R)		
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)		
SO DIUM BENZO ATE (UNII: OJ245FE5EU)		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:55315-385- 08	1 in 1 BOX	06/30/2015		
1		237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
2	NDC:55315-385- 04	1 in 1 BOX	06/30/2015		
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 FINAL	part341	06/30/2015		

Labeler - Freds Inc (005866116)

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