FIRST AID DIRECT COUGH RELIEF DM- guaifenesin dextromethorphan hbr syrup
Cintas Corporation

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.

First Aid Direct Cough Relief

Active ingredients (each 5mL/1 teaspoon)

- Dextromethorphan HBr 10mg
- Guaifenesin 100 mg

Purposes

cough suppressant

expectorant

Uses

temporarily:

- relieves coughing due to minor throat and bronchial irritation as may occur with a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

Warnings

Do not use

this product for persistent or chronic cough such as occurs with smoking, asthma, emphysema or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor. 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 are uncertain whether your prescription drug contains an MAOI, consult a health professional before taking this product.

Stop use and ask doctor if

- cough persists for more than 1 week, tends to recur 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.

Directions

do not take more than 6 doses in 24 hours, or as directed by a doctor.

- adults and children 12 years and over, take one premeasured single dose dispenser (2 teaspoons) every 4 hours
- children 6-11 years, measure out and take only 1 teaspoon every 4 hours
- children 2 to 5 years, measure out and take only 1/2 teaspoon every 4 hours
- children under 2 years, consult your doctor

Other information

- do not use if dispenser is torn, cut or opened
- store at room temperature
- avoid excessive heat and humidity

Inactive ingredients

citric acid, FD&C red 40, flavor, glycerin, methyl paraben, propylene glycol, propyl paraben, purified water, sodium citrate, sucralose

Questions?

1-800-327-2704

Package Label Principal Display Panel Single Dose Pack

BEND HERE

AND TEAR

Cough Relief DM

COUGH SUPPRESSANT EXPECTORANT

1/3 FL OZ (10 mL)

(2 Teaspoons)


BEND HERE
AND TEAR
COUGH
RELIEF DM
COUGH SUPPRESSANT
EXPECTORANT
Each 5 mL (1 teaspoon) contains:
Dextromethorphan HBr..... 10mg
Guaifenesin.....100mg
1/3 FL OZ (10 mL)
(2 Teaspoons)
KEEP OUT OF
REACH OF CHILDREN
Store at controlled room temperature,
between 20°C and 25°C (68°F and 77°F).

Package Label Principal Display Panel Box

Cough Relief DM

COUGH SUPPRESSANT

EXPECTORANT

LIQUID COUGH FORMULA

- **CONTROLS COUGHS**
- **LOOSENS and RELIEVES CHEST CONGESTIONS**
- **ALCOHOL-FREE**
- **NON DROWSY FORMULA**

6-10mL Doses per Box

FIRST AID DIRECT COUGH RELIEF DM

guaifenesin dextromethorphan hbr syrup

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:42961-121
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH)	DEXTROMETHORPHAN	10 mg

(DEXTROMETHORPHAN - UNII:7355X3ROTS)	HYDROBROMIDE	in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42961-121-02	6 in 1 BOX	05/13/2022	
1	NDC:42961-121-01	10 mL in 1 DOSE PACK; 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	05/13/2022	

Labeler - Cintas Corporation (056481716)

Establishment

Name	Address	ID/FEI	Business Operations
ULTRAtab Laboratories, Inc.		151051757	manufacture(42961-121)

Revised: 8/2022 Cintas Corporation