CORE VALUES TUSSIN CF- dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride solution

Harmon Stores 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.

Harmon Stores Inc. Tussin CF Drug Facts

Active ingredients (in each 10 mL)

Dextromethorphan HBr, USP 20 mg Guaifenesin, USP 200 mg Phenylephrine HCl, USP 10 mg

Purposes

Cough suppressant

Expectorant

Nasal decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes
- temporarily relieves these symptoms occurring with a cold:
- nasal congestion
- cough due to minor throat and bronchial irritation

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

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema

When using this product

do not use more than directed

Stop use and ask a doctor if

- you get nervous, dizzy, or sleepless
- symptoms do not get better within 7 days or are accompanied by fever
- 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 5 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

anhydrous citric acid, edetate disodium, FD&C red no. 40, flavor, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose

Principal Display Panel

Compare to active ingredients in Robitussin® Multi-Symptom Cold

For Ages 12 & Over

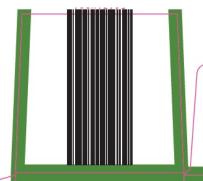
Adult

Tussin CF

Cough Suppressant (Dextromethorphan HBr)

Expectorant (Guaifenesin)

Nasal Decongestant (Phenylephrine HCl)
Multi-Symptom Cold
Peak Cold
Non-Drowsy
Relieves:
Cough
Nasal Congestion
Mucus
Cherry Flavor
Alcohol Free
8 FL OZ (237 mL)



CORE VALUES"

Compare to active ingredients in Robitussin® Multi-Symptom Cold*

For Ages 12 & Over

ussin

Cough Suppressant (Dextromethorphan HBr) Expectorant (Guaifenesin) Nasal Decongestant (Phenylephrine HCI)

Multi-Symptom Cold

Peak Cold Non-Drowsy

Relieves:

- Cough
- Nasal Congestion
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Cherry Flavor

8 FL OZ (237 mL)

CORE ALUES

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For Ages 12 & Over

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Multi-Symptom Cold

Peak Cold Non-Drowsy



- Cough
- Nasal Congestion
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Cherry Flavor

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Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of

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Inactive ingredients anhydrous citric acid, edetate disodium, FD&C red no. 40, flavor, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose



DO NOT USE IF PRINTED NECK IS BROKEN OR MISSING





LOT NO.

EXP.

CORE VALUES TUSSIN CF

dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride solution

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:63940-131 ORAL Route of Administration

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 10 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL	
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 10 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERIN (UNII: PDC6A3C0OX)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)		
SORBITOL (UNII: 506T60A25R)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		

Product Characteristics		
Color	RED (clear)	Score
Shape		Size
Flavor	FRUIT (Menthol)	Imprint Code
Contains		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:63940-131-34	1 in 1 CARTON	11/22/2016	
1	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	11/22/2016	

Labeler - Harmon Stores Inc. (804085293)

Revised: 2/2020 Harmon Stores Inc.