TOPCARE TUSSIN CF MAX- dextromethorphan hbr, guaifenesin, phenylephrine hcl suspension Topco Associates 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.

Topco Associates LLC. Tussin CF Max Drug Facts

Active ingredients (in each 10 mL)

Dextromethorphan HBr, USP 20 mg Guaifenesin, USP 400 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

- shake well before using
- 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 7 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

Inactive Ingredients

anhydrous citric acid, FD&C red no. 40, flavor, glycerin, menthol, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose, xanthan gum

Questions or comments?

1-888-423-0139

Package/Label Principal Display Panel

FOR ADULTS For Ages 12 & Over PEAK COLD Tussin CF MaxCOUGH SUPPRESSANT (Dextromethorphan HBr)EXPECTORANT (Guaifenesin)NASAL DECONGESTANT (Phenylephrine HCl)Multi-SymptomColdMaximum StrengthNon-DrowsyRelieves:Nasal CongestionCoughMucusCOMPARE TO ROBITUSIN® MAXIMUM STRENGTH MULTI-SYMPTOM COLD active

4 FL OZ (118 mL)



TOPCARE TUSSIN CF N	ЛАХ		
dextromethorphan hbr, guaifenesin	n, phenylephrine hcl suspens	sion	
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-296
Route of Administration	ORAL		

	Ingredient Name	Basis of Stre	ngth Strengtl
DEXTROMETHORPH A (DEXTROMETHORPHA)	AN HYDROBROMIDE (UNII: 9 D2RTI9KYH) N - UNII:7355X3ROTS)	DEXTRO METHO RPH HYDRO B RO MIDE	AN 20 mg in 10 mL
GUAIFENESIN (UNII: 4	95W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 10 mL
PHENYLEPHRINE HYI UNII:1WS297W6MV)	DRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 10 mL
Inactive Ingredie	nts		
	Ingredient Name		Strength
ANHYDRO US CITRIC	ACID (UNII: XF417D3PSL)		
FD&C RED NO.40 (UI	NII: WZB9127XOA)		
GLYCERIN (UNII: PDC	6A3C0OX)		
MENTHOL (UNII: L7T1	0EIP3A)		
POLYETHYLENE GLY	YCOL (UNII: 3WJQ0SDW1A)		
PROPYLENE GLYCO	L (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0	KO0R)		
SODIUM BENZOATE	(UNII: OJ245FE5EU)		
SODIUM CITRATE (UI	NII: 1Q73Q2JULR)		
SORBITOL (UNII: 506	T60A25R)		
SUCRALOSE (UNII: 96	K6UQ3ZD4)		
SORBITOL (UNII: 506 SUCRALOSE (UNII: 96 XANTHAN GUM (UNII:	K6UQ3ZD4)		
SUCRALOSE (UNII: 96	K6UQ3ZD4)		
SUCRALOSE (UNII: 96 XANTHAN GUM (UNII:	K6UQ3ZD4) TTV12P4NEE)		
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SUCRALOSE (UNII: 96 XANTHAN GUM (UNII: Product Characte Color	K6UQ3ZD4) TTV12P4NEE) ristics	Score Size	
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SUCRALOSE (UNII: 96 XANTHAN GUM (UNII: Product Characte Color Shape Flavor Contains	K6UQ3ZD4) TTV12P4NEE)	Size	
SUCRALOSE (UNII: 96 XANTHAN GUM (UNII: Product Characte Color Shape Flavor Contains Packaging	K6UQ3ZD4) TTV12P4NEE) ristics RED FRUIT PUNCH, MENTHOL	Size Imprint Code	Marketing End Dat
SUCRALOSE (UNII: 96 XANTHAN GUM (UNII: Product Characte Color Shape Flavor Contains Packaging # Item Code	K6UQ3ZD4) TTV12P4NEE) RED FRUIT PUNCH, MENTHOL Package Description	Size Imprint Code Marketing Start Date	Marketing End Dat
SUCRALOSE (UNII: 96 XANTHAN GUM (UNII: Product Characte Color Shape Flavor Contains Packaging # Item Code 1 NDC:36800-296-26	K6UQ3ZD4) TTV12P4NEE) TTV12P4NEE) TTV12P4NEE) TRED RED FRUIT PUNCH, MENTHOL Package Description 1 in 1 CARTON	Size Imprint Code	Marketing End Dat
SUCRALOSE (UNII: 96 XANTHAN GUM (UNII: Product Characte Color Shape Flavor Contains Packaging # Item Code 1 NDC:36800-296-26 1	K6 UQ3ZD4) TTV12P4NEE) RED FRUIT PUNCH, MENTHOL FRUIT PUNCH, MENTHOL Package Description 1 in 1 CARTON 1 is mL in 1 BOTTLE; Type 0: Not a Combination Product	Size Imprint Code Marketing Start Date 08/08/2012	Marketing End Dat
SUCRALOSE (UNII: 96 XANTHAN GUM (UNII: Product Characte Color Shape Flavor Contains Packaging # Item Code 1 NDC:36800-296-26 1 2 NDC:36800-296-34	KGUQ3ZD4) TTV12P4NEE) RED FRUIT PUNCH, MENTHOL FRUIT PUNCH, MENTHOL I T CARTON 118 mL in 1 BOTTLE; Type 0: Not a Combination Product 1 in 1 CARTON	Size Imprint Code Marketing Start Date	Marketing End Dat
SUCRALOSE (UNII: 96 XANTHAN GUM (UNII: Color Shape Flavor Contains	K6 UQ3ZD4) TTV12P4NEE) RED FRUIT PUNCH, MENTHOL FRUIT PUNCH, MENTHOL Package Description 1 in 1 CARTON 1 is mL in 1 BOTTLE; Type 0: Not a Combination Product	Size Imprint Code Marketing Start Date 08/08/2012	Marketing End Dat
SUCRALOSE (UNII: 96 XANTHAN GUM (UNII: Color Shape Flavor Contains	KGUQ3ZD4) TTV12P4NEE) RED FRUIT PUNCH, MENTHOL FRUIT PUNCH, MENTHOL I T CARTON 118 mL in 1 BOTTLE; Type 0: Not a Combination Product 1 in 1 CARTON	Size Imprint Code Marketing Start Date 08/08/2012	Marketing End Dat
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SUCRALOSE (UNII: 96 XANTHAN GUM (UNII: Product Characte Color Shape Flavor Contains Packaging # Item Code 1 NDC:36800-296-26 1 NDC:36800-296-34 2 NDC:36800-296-34	KGUQ3ZD4) TTV12P4NEE) RED RED FRUIT PUNCH, MENTHOL FRUIT PUNCH, MENTHOL 1 in 1 CARTON 1 in 1 CARTON 1 is mL in 1 BOTTLE; Type 0: Not a Combination Product 1 in 1 CARTON 2 37 mL in 1 BOTTLE; Type 0: Not a Combination Product	Size Imprint Code 8 08/08/2012 08/08/2012	
SUCRALOSE (UNII: 96 XANTHAN GUM (UNII: Product Characte Color Shape Flavor Contains Packaging	KGUQ3ZD4) TTV12P4NEE) RED RED FRUIT PUNCH, MENTHOL FRUIT PUNCH, MENTHOL Package Description 1 in 1 CARTON 118 mL in 1 BOTTLE; Type 0: Not a Combination Product 1 in 1 CARTON 237 mL in 1 BOTTLE; Type 0: Not a Combination Product 1 in 1 CARTON	Size Imprint Code Marketing Start Date 08/08/2012	Marketing End Date

Labeler - Topco Associates LLC (006935977)