TOPCO TUSSIN CF MAX- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl solution 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 20 mL)

Acetaminophen, USP 650 mg
Dextromethorphan HBr, USP 20 mg
Guaifenesin, USP 400 mg
Phenylephrine HCl, USP 10 mg

Purposes

Pain reliever/fever reducer
Cough suppressant
Expectorant
Nasal decongestant

Uses

- temporarily relieves these symptoms occurring with a cold or flu:
- cough due to minor throat and bronchial irritation
- nasal congestion
- sinus congestion and pressure
- minor aches and pains
- sore throat
- headache
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen

• 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

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.
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin

When using this product do not use more than directed

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- pain, cough, or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days

- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts. 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.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- do not take more than 5 doses in any 24-hour period
- do not exceed recommended dosage. Taking more than the recommended dose (overdose) may cause serious liver damage.
- 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	20 mL every 4 hours
children under 12 years	do not use

Other information

- each 20 mL contains: sodium 15 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

anhydrous citric acid, benzyl alcohol, edetate disodium, FD&C red #40, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose, triacetin, xanthan gum

Questions or comments?

1-888-423-0139

Package/Label Principal Display Panel

TopCare® he	ealth
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COMPARE TO ROBITUSSIN® MAXIMUM STRENGTH SEVERE MULTI-SYMPTOM

COUGH COLD + FLU ACTIVE INGREDIENTS

NON-DROWSY

Tussin CF Max

Multi-Symptom Cough, Cold & Flu

PAIN RELIEVER/FEVER REDUCER-ACETAMINOPHEN

COUGH SUPPRESSANT-DEXTROMETHORPHAN HBr

EXPECTORANT-GUAIFENESIN

NASAL DECONGESTANT-PHENYLEPHRINE HCI

MAXIMUM STRENGTH

SEVERE

RELIEVES:

- Cough, Sore Throat
- Body Aches, Fever
- Nasal Congestion
- Chest Congestion

Adult

For Ages 12 & Over

4 FL OZ (118 mL)



Multi-Symptom

EXPECTORANT-GUAIFENESIN

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· Body Aches, Fever

Nasal Congestion

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Drug Facts

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Drug Facts (continued)

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●TopCare •

Cough, Cold &Flu Multi-Symptom CF Max

NON-DEOMSK

- Ask a doctor before use if you have
- liver disease heart disease thyroid disease diabetes
- high blood pressure
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Questions or comments? 1-888-423-0139

DISTRIBUTED BY TOPCO ASSOCIATES LLC ELK GROVE VILLAGE, IL 60007

©TOPCO PERA0521 QUESTIONS? 1-888-423-0139
topcare@topco.com www.topcarebrand.com



This TopCare® product is laboratory tested to quarantee its highest quality. Your total satisfaction is guaranteed.

information or call 1-888-423-0139

GF) GLUTEN FREE

*This product is not manufactured or distributed by Pfizer, distributor of Robitussin® Maximum Strength Severe Multi-Symptom Cough Cold + Flu.

DO NOT USE IF PRINTED NECKBAND OR MISSING







7C126 88 C3

TOPCO TUSSIN CF MAX

acetaminophen, dextromethorphan hbr, quaifenesin, phenylephrine hcl solution

Product Information

HUMAN OTC DRUG **Product Type** Item Code (Source) NDC:36800-707

Route of Administration

ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg in 20 mL	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL	

BENZYL ALCOHOL (UNII: LKG8494WBH) EDETATE DISODIUM (UNII: 7FLD91C86K) FD&C RED NO. 40 (UNII: WZB9127XOA) GLYCERIN (UNII: PDC6A3C0OX) POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) WATER (UNII: 059QF0KOOR) SODIUM BENZOATE (UNII: OJ245FE5EU)	Inactive Ingredients		
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SODIUM BENZOATE (UNII: OJ245FE5EU)	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
	WATER (UNII: 059QF0KO0R)		
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	SODIUM BENZOATE (UNII: OJ245FE5EU)		
	SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)		
SUCRALOSE (UNII: 96K6UQ3ZD4)	SUCRALOSE (UNII: 96K6UQ3ZD4)		
TRIACETIN (UNII: XHX3C3X673)	TRIACETIN (UNII: XHX3C3X673)		
XANTHAN GUM (UNII: TTV12P4NEE)	XANTHAN GUM (UNII: TTV12P4NEE)		
SORBITOL (UNII: 506T60A25R)	SORBITOL (UNII: 506T60A25R)		

Product Characteristics			
Color	RED	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-707- 26	1 in 1 CARTON	09/11/2017	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:36800-707- 34	1 in 1 CARTON	09/14/2017	
2		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	09/11/2017	

Labeler - Topco Associates LLC (006935977)

Revised: 8/2022 Topco Associates LLC