TUSSIN- guaifenesin solution
Strategic Sourcing Services

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.

Tussin
GuaifenesinOral Solution, USP

ACTIVE INGREDIENT(S)

Guaifenesin, USP 200 mg

PURPOSE

Expectorant

USE(S)

helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

WARNINGS

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

WHEN USING THIS PRODUCT

■ do not use more than directed

STOP USE AND ASK DOCTOR IF

■ cough lasts more than 7 days, comes back, or occurs with 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 right away (1-800-222-1222).

DIRECTIONS

■ do not take more than 6 doses in any 24-hour period.
■ this adult strength product is not intended for use in children under 12 years of age
■ mL = milliliter
■ measure only with dosing cup provided
■ keep dosing cup with product

Age	Dose
Adults and children 12 years and over	10 – 20 mL every 4 hours
Children under 12 years	do not use

Other information

■ **each 10 mL contains:**sodium 6 mg
■ store between 20-25°C (68-77°F)
■ do not refrigerate
■ **Keep carton for full directions for use**

Inactive ingredients

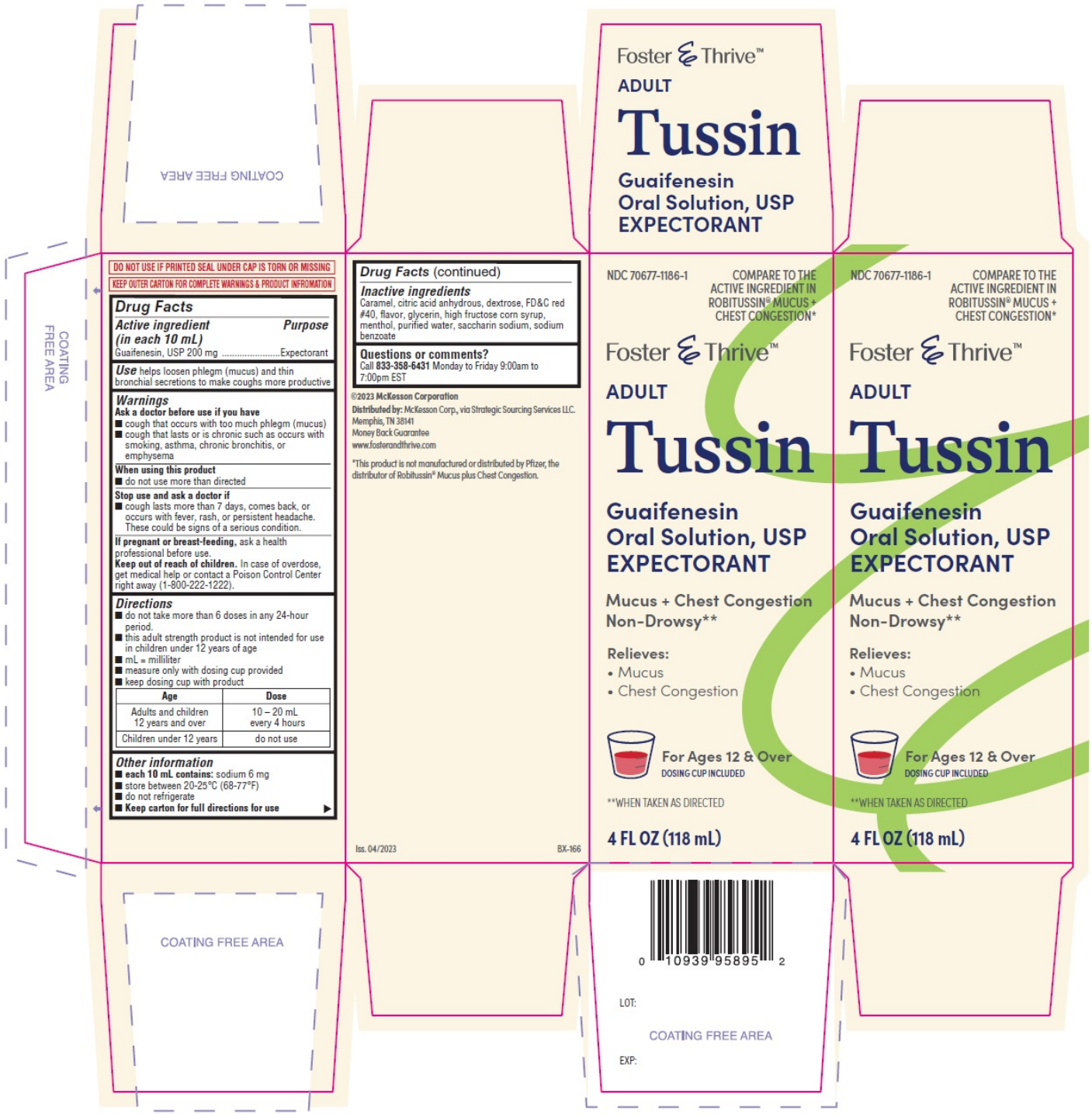
Caramel, citric acid anhydrous, dextrose, FD&C red #40, flavor, glycerin, high fructose corn syrup, menthol, purified water, saccharin sodium, sodium benzoate

Questions or comments?

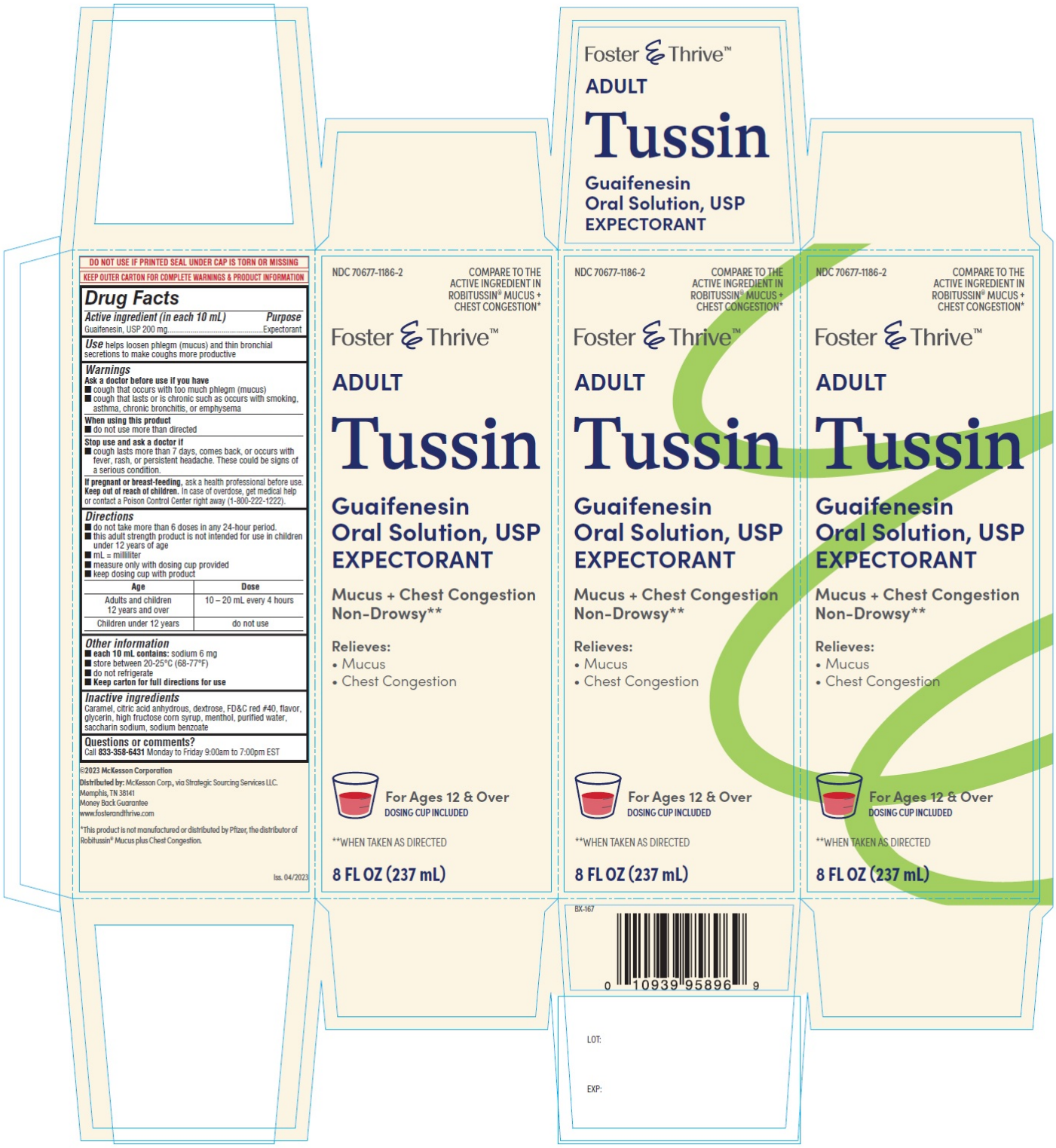
Call **833-358-6431**Monday to Friday 9:00am to 7:00pm EST

PRINCIPAL DISPLAY PANEL

Guaifenesin oral solution USP-118 mL



Guaifenesin oral solution USP-237 mL



TUSSIN

guaifenesin solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70677-1186
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
CARAMEL (UNII: T9D99G2B1R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
DEXTROSE (UNII: IY9XDZ35W2)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
MENTHOL (UNII: L7T10EIP3A)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677-1186-1	1 in 1 CARTON	08/09/2023	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70677-1186-2	1 in 1 CARTON	08/09/2023	
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	08/09/2023	

Labeler - Strategic Sourcing Services (116956644)

Establishment

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(70677-1186)

Revised: 8/2023 Strategic Sourcing Services