SORBUGEN- dextromethorphan hydrobromide, glycerol guaiacolate syrup
Kramer Novis

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.

SORBUGEN® NR

Drug Facts

Active Ingredients (in each 7.5 mL 1½ tsp)

Dextromethorphan HBr, 15 mg

Glyceryl Guaiacolate (Guaifenesin), 150 mg

Purposes

Antitussive

Expectorant

Uses

- for the temporary relief of cough due to minor throat and bronchial irritation as may occur with a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passages of bothersome mucus, drain bronchial tubes, and make coughs more productive

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
• 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
• coughs lasts more than 7 days, comes back, or is accompanied by fever, rash, or a 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 accidental overdose, get medical help or contact a Poison Control Center right away.

Directions

do not take more than 6 doses in any 24-hour period

4 HOURS EVERY	Adults and Children 12 years of age and over	10 mL (2 tsp)
	Children 6 to under 12 years of age	5 mL (1 tsp)
	Children 2 to under 6 years of age	2.5 mL (½ tsp)
	Children under 2 years of age	Consult physician

Other information

- Tamper evident feature: Do not use if inner seal is torn, broken or missing.
- Store at controlled room temperature 15-30°C (59-86°F).
- Avoid excessive heat or humidity.

Inactive Ingredients

Citric acid, glycerin, grape flavor, methyl paraben, potassium citrate, potassium sorbate, propyl paraben, purified water, sucralose

Contains the same active ingredients as Sorbutuss® NR*

Dextromethorphan HBr

ANTITUSSIVE

Glyceryl Guaiacolate (Guaifenesin)

EXPECTORANT

Antihistamine & Decongestant Free

SUGAR DYE & ALCOHOL FREE

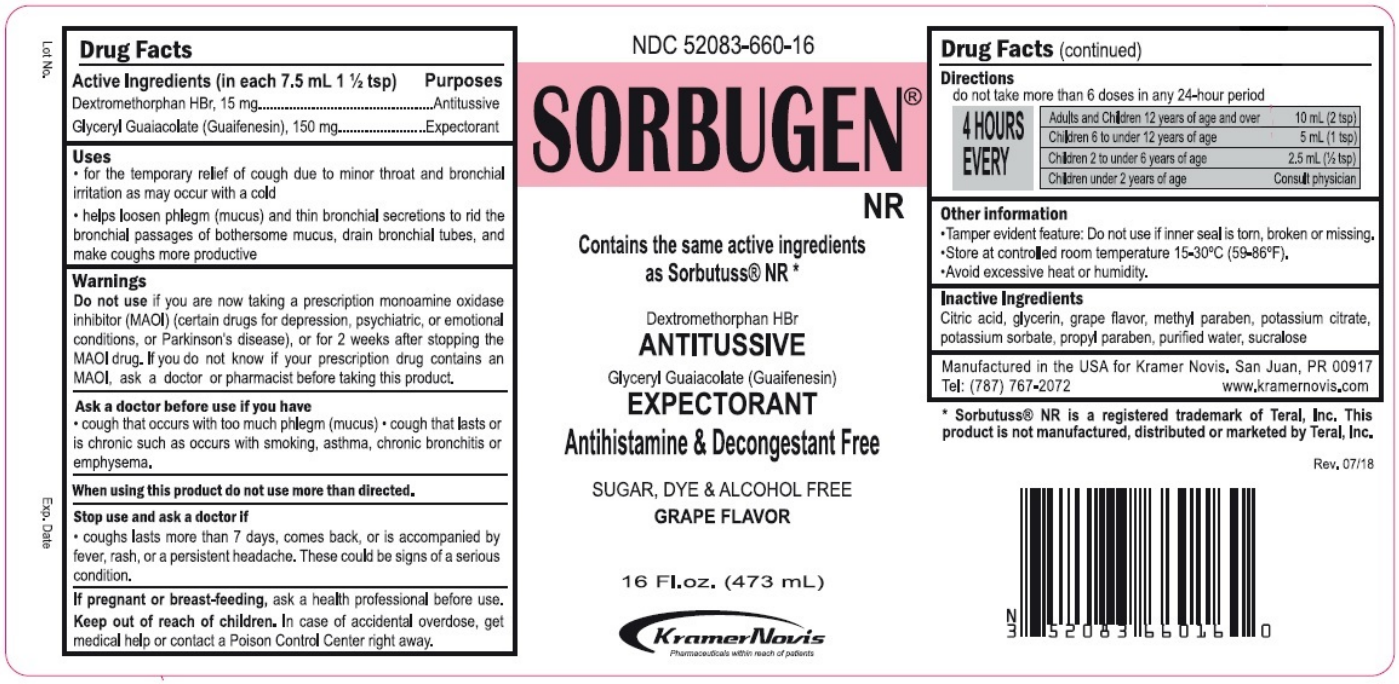
GRAPE FLAVOR

Manufactured in the USA for Kramer Novis. San Juan, PR 00917

Tel: (787) 767-2072 www.kramernovis.com

*** Sorbutuss® NR is a registered trademark of Teral, Inc. This product is not manufactured, distributed or marketed by Teral, Inc.**

Packaging



SORBUGEN

dextromethorphan hydrobromide, glycerol guaiacolate syrup

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52083-660
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg in 7.5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	150 mg in 7.5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		**Score**	

Shape		**Size**	
Flavor	GRAPE (SWEET GRAPE)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52083-660-16	480 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/08/2014	

Labeler - Kramer Novis (090158395)

Registrant - Kramer Novis (090158395)

Revised: 12/2018 Kramer Novis