SORBUTUSS NR- sorbutuss liquid
Dextrum Laboratories Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use Sorbutuss. See full prescribing information for Initial U.S. Approval
OTC Monograph

INDICATIONS AND USAGE

- 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 makes cough more productive.

DOSAGE AND ADMINISTRATION

Follow dosage below or use as directed by a doctor. Do not exceed 6 doses in a 24 hours period. (8)
(8)
Adults and children 12 years and older 2 teaspoonfuls every 4 hours (8)
(8)
Children 6 years to under 6 years 1 teaspoonful every 4 hours (8)
(8)
Children 2 years to 6 years 1/2 teaspoonful every 4 hours (8)
(8)
Children under 2 years Consult a doctor (8)

Revised: 1/2007

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

Active Ingredients

Each 7.5 mL. Contains (1 1/2 tsp)

Dextromethorphan HBr 15 mg.....Antitussive

Glyceryl Guaiacolate 150 mg....Expectorant

Purpose Section

Antitusive

Expectorant

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- 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 makes cough 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

- Chronic cough that last such as occurs with smoking, asthma, chronic bronchitis or emphysema.
- Cough that occurs with too much phlegm (mucus).

Stop use and ask a doctor if

- Cough last for more than 7 days comes back or occurs with fever, rash or persistent headache. A persistent cough may be a sign of a serious condition.

Pregnancy or breast feeding section

If pregnant or breast-feeding, ask a health professional before use

Keep out of reach of children

In a case of overdose, get medical help or contact a Poison Control Center right away.

These highlights do not include all the information needed to use

Follow dosage below or use as directed by a doctor. Do not exceed 6 doses in a 24 hours period.

Adults and children 12 years and older 2 teaspoonfuls every 4 hours

Children 6 years to under 6 years 1 teaspoonful every 4 hours

Children 2 years to 6 years 1/2 teaspoonful every 4 hours

Children under 2 years Consult a doctor

Other information

Store at room temperature 15º-30º C (59º - 86º F)

Inactive Ingredients

Artificial and Natural Flavors, Glycerin, Methylparaben, Potassium Citrate, Propylparaben, Purified Water, Sorbitol and Sucralose

Questions or Comments?

Teral, Inc. (787) 383-2781 Fax (787) 284-9082

Safety Information

Do not accept if safety seal around bottle cap is broken or missing

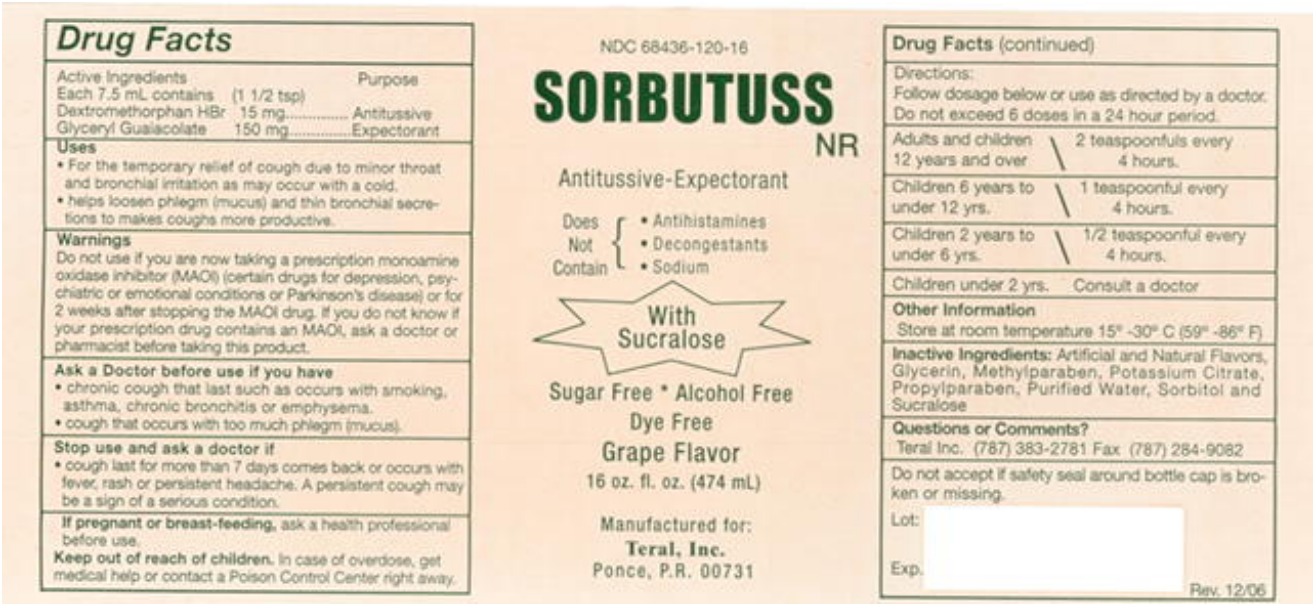
Expiration Date information

Lot:

Exp:

Rev:12/06

Principal Panel



NDC 68436-120-16

Sorbutuss NR

Antitussive-Expectorant

Does Not Containt

Antihistamines

Decongestants

Sodium

With

Sucralose

Sugar Free Alcohol Free

Dye Free

Grape Flavor

16 oz. fl. oz. (474 mL)

Manufacture for

Teral, Inc.

Ponce, P.R. 00731

SORBUTUSS NR

sorbutuss liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68436-120
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
POTASSIUM CITRATE (UNII: EE90ONI6FF)	

Product Characteristics			
Color		**Score**	

Shape		**Size**	
Flavor	ORANGE (with Sucralose)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68436-120-16	474 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	01/01/2007	

Labeler - Dextrum Laboratories Inc. (186958810)

Registrant - Teral Inc (186958810)

Establishment

Name	Address	ID/FEI	Business Operations
Dextrum Laboratories, Inc		007392322	manufacture(68436-120)

Revised: 12/2024 Dextrum Laboratories Inc.