

**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\***

**Active Ingredients**

Purpose Section

**These highlights do not include all the information needed to use Sorbutuss. See full prescribing information for Initial U.S. Approval**

**Warnings**

**Ask A Doctor Before use if you have**

**Stop use and ask a doctor if**

**Pregnancy or breast feeding section**

**Keep out of reach of children**

**These highlights do not include all the information needed to use**

\* 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

## **These highlights do not include all the information needed to use Sorbutuss. See full prescribing information for Initial U.S. Approval**

- 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 15°-30° C (59° - 86° 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

<b>Drug Facts</b> Active Ingredients Each 7.5 mL contains (1 1/2 tsp) Dextromethorphan HBr 15 mg..... Antitussive Glyceryl Guaiacolate 150 mg..... Expectorant <b>Purpose</b> <b>Uses</b> • 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 coughs more productive. <b>Warnings</b> 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. <b>Ask a Doctor before use if you have</b> • chronic cough that last such as occurs with smoking, asthma, chronic bronchitis or emphysema. • cough that occurs with too much phlegm (mucus). <b>Stop use and ask a doctor if</b> • 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. <b>If pregnant or breast-feeding, ask a health professional before use.</b> <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.	NDC 68436-120-16 <b>SORBUTUSS</b> NR Antitussive-Expectorant Does Not Contain { • Antihistamines • Decongestants • Sodium <b>With Sucralose</b> Sugar Free * Alcohol Free Dye Free Grape Flavor 16 oz. fl. oz. (474 mL) Manufactured for: <b>Teral, Inc.</b> Ponce, P.R. 00731	<b>Drug Facts (continued)</b> <b>Directions:</b> Follow dosage below or use as directed by a doctor. Do not exceed 6 doses in a 24 hour period. Adults and children 12 years and over \ 2 teaspoonfuls every 4 hours. Children 6 years to under 12 yrs. \ 1 teaspoonful every 4 hours. Children 2 years to under 6 yrs. \ 1/2 teaspoonful every 4 hours. Children under 2 yrs. Consult a doctor <b>Other Information</b> Store at room temperature 15° -30° C (59° -86° F) <b>Inactive Ingredients:</b> Artificial and Natural Flavors, Glycerin, Methylparaben, Potassium Citrate, Propylparaben, Purified Water, Sorbitol and Sucralose <b>Questions or Comments?</b> Teral Inc. (787) 383-2781 Fax (787) 284-9082 Do not accept if safety seal around bottle cap is broken or missing. Lot: <input type="text"/> Exp. <input type="text"/> Rev. 12/06
--	---	---

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

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68436-120
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII: 7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>POTASSIUM CITRATE</b> (UNII: EE90ONI6FF)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
--------------	--	--------------	--

<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	ORANGE (with Sucralose)	<b>Imprint Code</b>	
<b>Contains</b>			

### 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: 12/2025

Dextrum Laboratories Inc.