

GILTUSS CHILDRENS COUGH AND CHEST CONGESTION- dextromethorphan hydrobromide, guaifenesin solution

Dextrum Laboratories, Inc

Indication and usage section

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Not take more than 6 doses in any 24 hours period.

Use enclosed dosing cup. keep dosage cup for use with this product

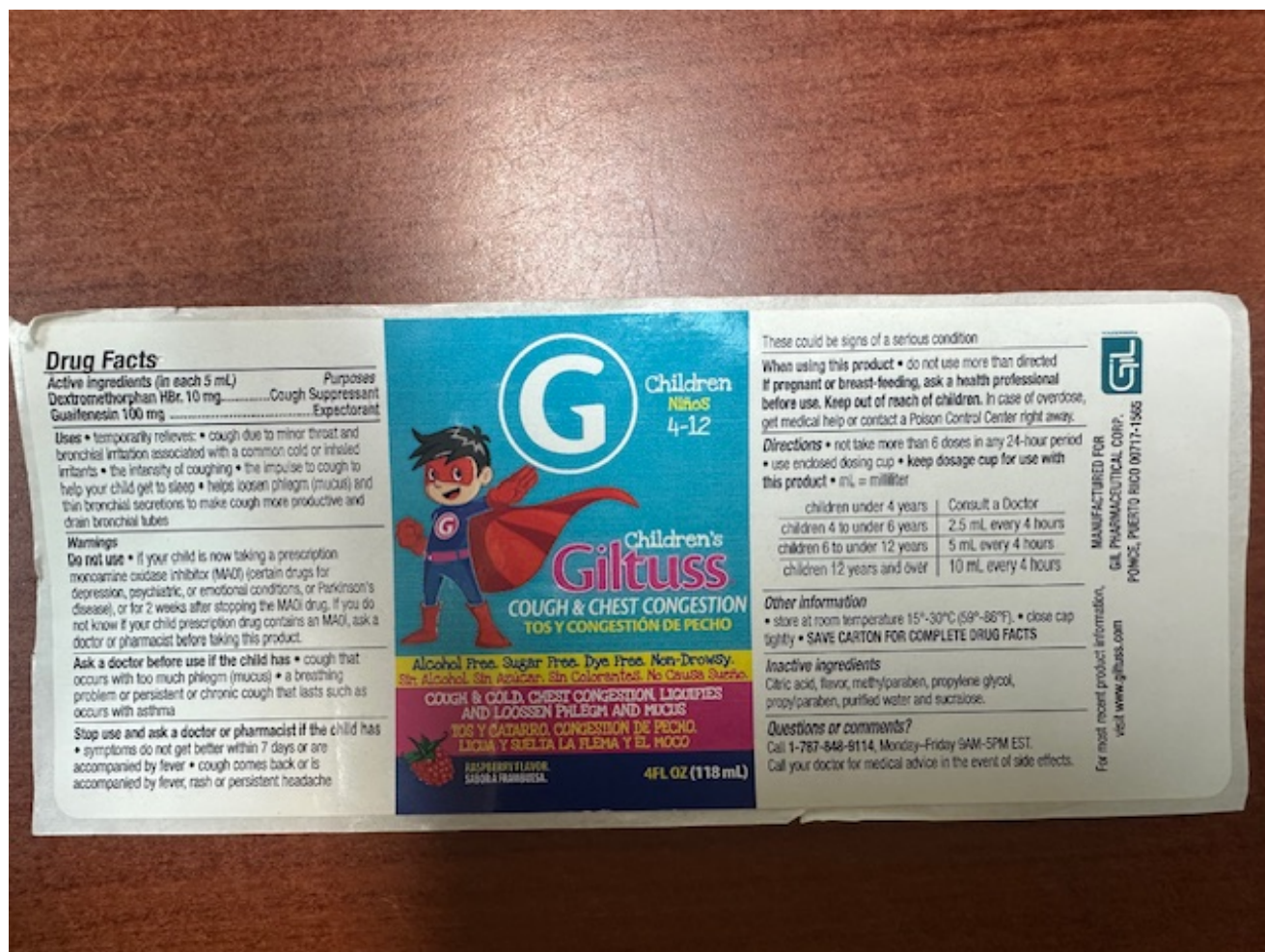
ML=Milliliters

Children under 4 years, consult a doctor

Children 4 to under 6 years, 2.5 ml every 4 hours

Children 6 to under 12 years, 5 ml every 4 hours

Children 12 years and over, 10 ml every 4 hours



Active ingredient section

Active ingredient section

(in each 5 mL)

Dextromethorphan HBr 10 mg

Guaifenesin 100 mg

Drug Facts

Active Ingredients (in each 5 mL)	Purposes
Dextromethorphan HBr, 10 mg	Cough Suppressant
Guaifenesin 100 mg	Expectorant

Uses • temporarily relieves: • cough due to minor throat and bronchial irritation associated with a common cold or inhaled irritants • the intensity of coughing • the impulse to cough to help your child get to sleep • helps loosen phlegm (mucus) and thin bronchial secretions to make cough more productive and drain bronchial tubes

Warnings
Do not use • if your child is 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 child prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if the child has • cough that occurs with too much phlegm (mucus) • a breathing problem or persistent or chronic cough that lasts such as occurs with asthma

Stop use and ask a doctor or pharmacist if the child has • symptoms do not get better within 7 days or are accompanied by fever • cough comes back or is accompanied by fever, rash or persistent headache

Children 4-12

Children's Giltuss
COUGH & CHEST CONGESTION
TOS Y CONGESTIÓN DE PECHO

Alcohol Free, Sugar Free, Dye Free, Non-Drowsy.
Sin Alcohol, Sin Azúcar, Sin Colorantes, No Causa Somnolencia.

COUGH & COLD, CHEST CONGESTION, LIQUIDS
AND LOOSENS PHLEGM AND MUCUS
TOS Y CATARRO, CONGESTIÓN DE PECHO,
LÍQUIDA Y SUELTA LA FLEMA Y EL MOCO

RASPBERRY FLAVOR,
SABOR A FRAMBUESA.

4 FL OZ (118 mL)

These could be signs of a serious condition

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Other information
• store at room temperature 15°-30°C (59°-86°F). • close cap tightly • **SAVE CARTON FOR COMPLETE DRUG FACTS**

Inactive ingredients
Citric acid, flavor, methylparaben, propylene glycol, propylparaben, purified water and sucralose.

Questions or comments?
Call 1-767-848-6114, Monday-Friday 9AM-5PM EST.
Call your doctor for medical advice in the event of side effects.

MANUFACTURED FOR
GIL PHARMACEUTICAL CORP.
PO BOX 10000, PUEBLO, CO 81001-1000

For most recent product information,
visit www.giltuss.com

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MANUFACTURED FOR
GIL PHARMACEUTICAL CORP.
CONDOM, PUERTO RICO 00717-1405

For most recent product information,
visit www.allergan.com

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Purpose section

Drug Facts

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Guaifenesin 100 mg Expectorant

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GIL PHARMACEUTICAL CORP.
PONCE, PUERTO RICO 00717-1565

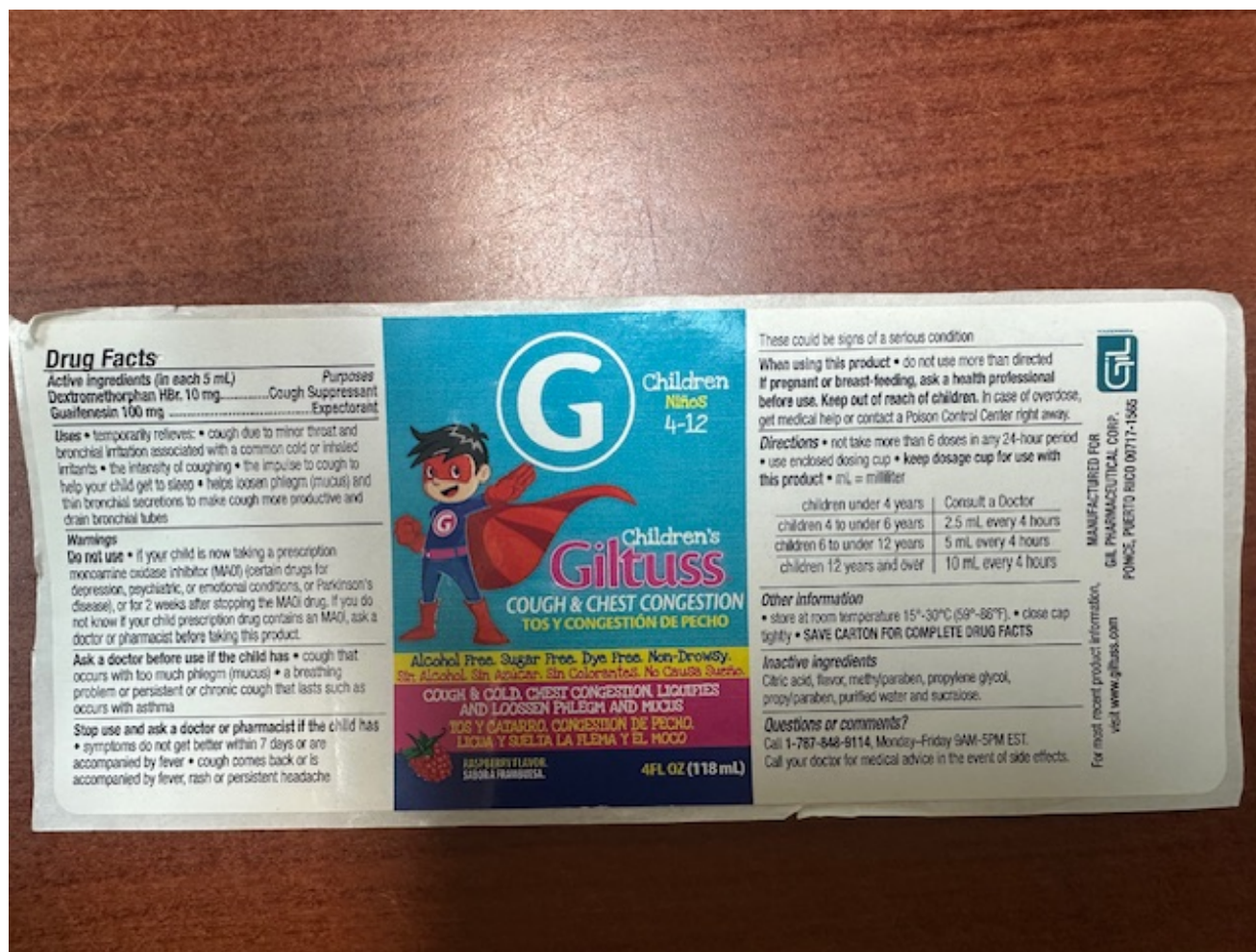
For most recent product information,
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Purpose section

Cough suppressant

Expectorant

Warnings



Warnings

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Keep out of reach of childrens section

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Children's
Niños
4-12

G

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Giltuss
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MANUFACTURED FOR
GIL PHARMACEUTICAL CORP.
PONCE, PUERTO RICO 00717-1565

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Ask a doctor section

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PONCE, PUERTO RICO 00717-1565

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Ask a doctor section

Ask a doctor before use if the child has
cough that occurs with much phlegm(mucus)

a breathing problem or persistent or chronic cough that lasts such as occurs with
asthma.

stop use section

Drug Facts

Active ingredients (in each 5 mL)


Dextromethorphan HBr, 10 mg	Purposes
Guafenesin 100 mg	Cough Suppressant
	Expectorant

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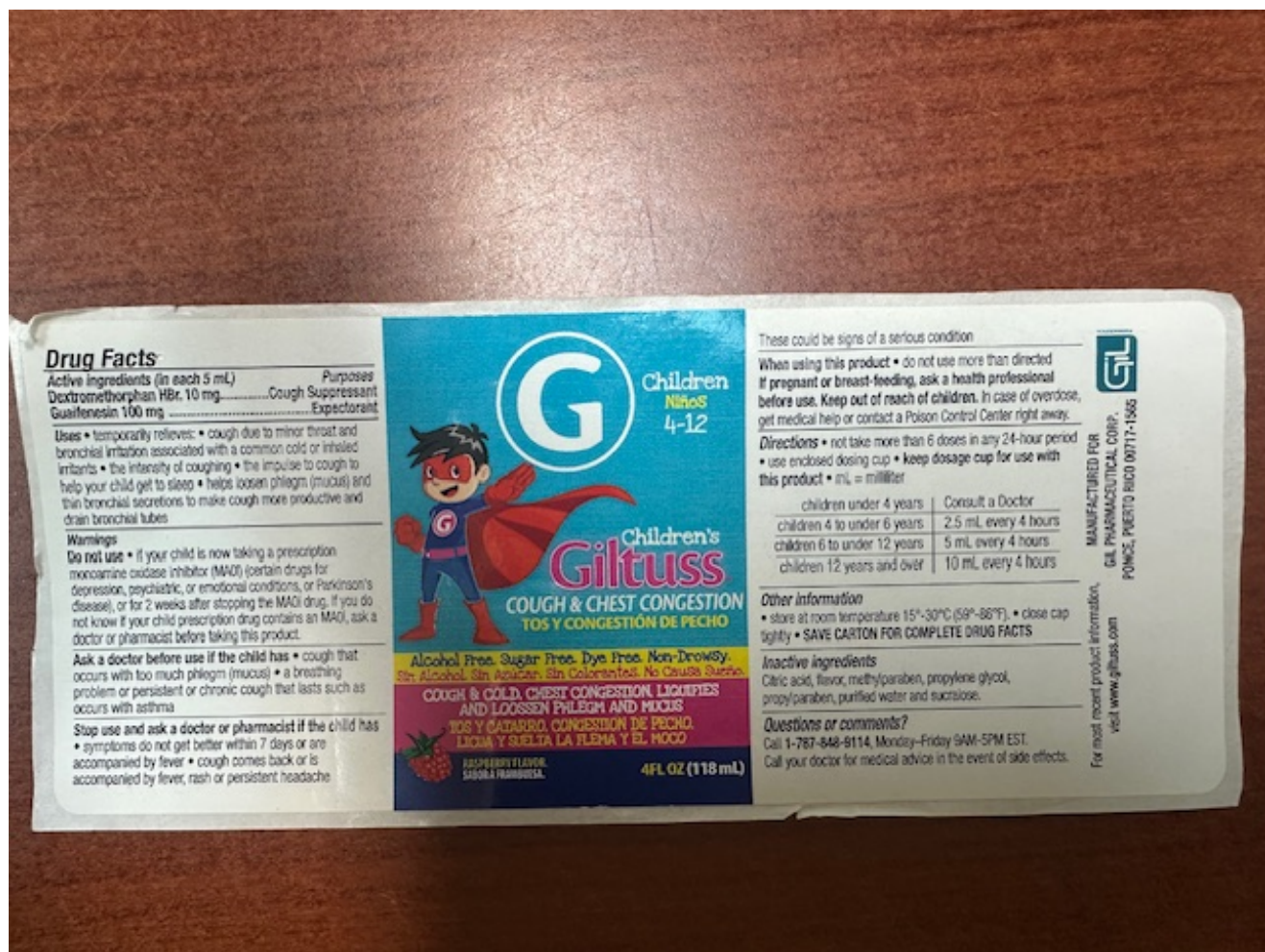
MANUFACTURED FOR
GIL PHARMACEUTICAL CORP.
PONCE, PUERTO RICO 00717-1565

For most recent product information, visit www.giltuss.com

stop use section

Stop use and ask doctor or pharmacist if the child has symptoms do not get better within 7 days or are accompanied by fever, cough comes back or is accompanied by fever rash or persistent headache.

Dosage and Administration section



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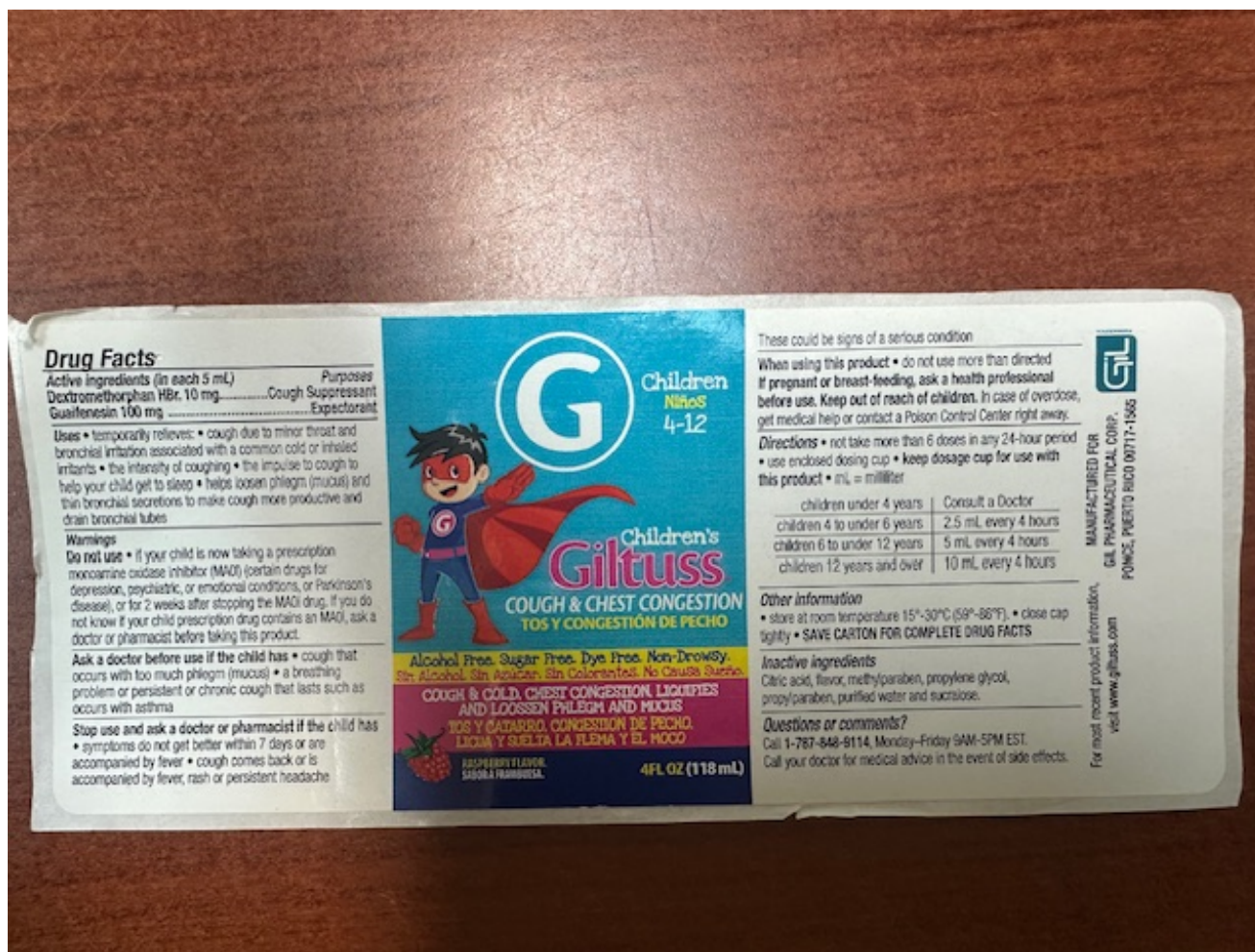
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Package Label. Principal Display Panel



Package Label. Principal Display Panel

G Children, niños 4-12

Children's

Giltuss

Cough & Chest Congestion

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LIQUA Y SUELTA LA FLEMA Y EL MOCO

RASBERRY FLAVOIR.

SABOR A FRAMBUESA. 4 FL OZ (118 ml)

GILTUSS CHILDRENS COUGH AND CHEST CONGESTION

dextromethorphan hydrobromide, guaifenesin solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65852-019
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	
CITRIC ACID (UNII: 2968PHW8QP)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	RASPBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65852-019-04	1 in 1 CARTON	10/02/2018	
1		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	10/02/2018	

Labeler - Dextrum Laboratories, Inc (007392322)

