

LUGOLS STRONG IODINE- iodine and potassium iodide solution
CooperSurgical, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Lugols Strong Iodine Solution

CONTENTS

Iodine 0.05 g/ml, Potassium Iodide 0.100 g/ml.

DESCRIPTION

LUGOL'S is an aqueous solution containing Iodine 5%, and potassium iodide 10%, w/v (LUGOL's Solution). LUGOL's is a transparent liquid with a deep brown color and the odor of iodine.

HOW SUPPLIED

LUGOL'S is supplied in 8 ml glass single-use bottles.

INDICATIONS AND USAGE

LUGOL's is a topical antiseptic. Strong Iodine Solution is a germicide and fungicide. LUGOL's is preservative-free.

ADMINISTRATION

LUGOL'S is applied directly to areas needing antiseptic.

WARNINGS

For External Use Only.

CONTRAINDICATIONS

Iodide preparations are contraindicated in patients with known sensitivity to the drugs.

CAUTION

Federal law restricts this device to sale by or on the order of a physician.

STORAGE

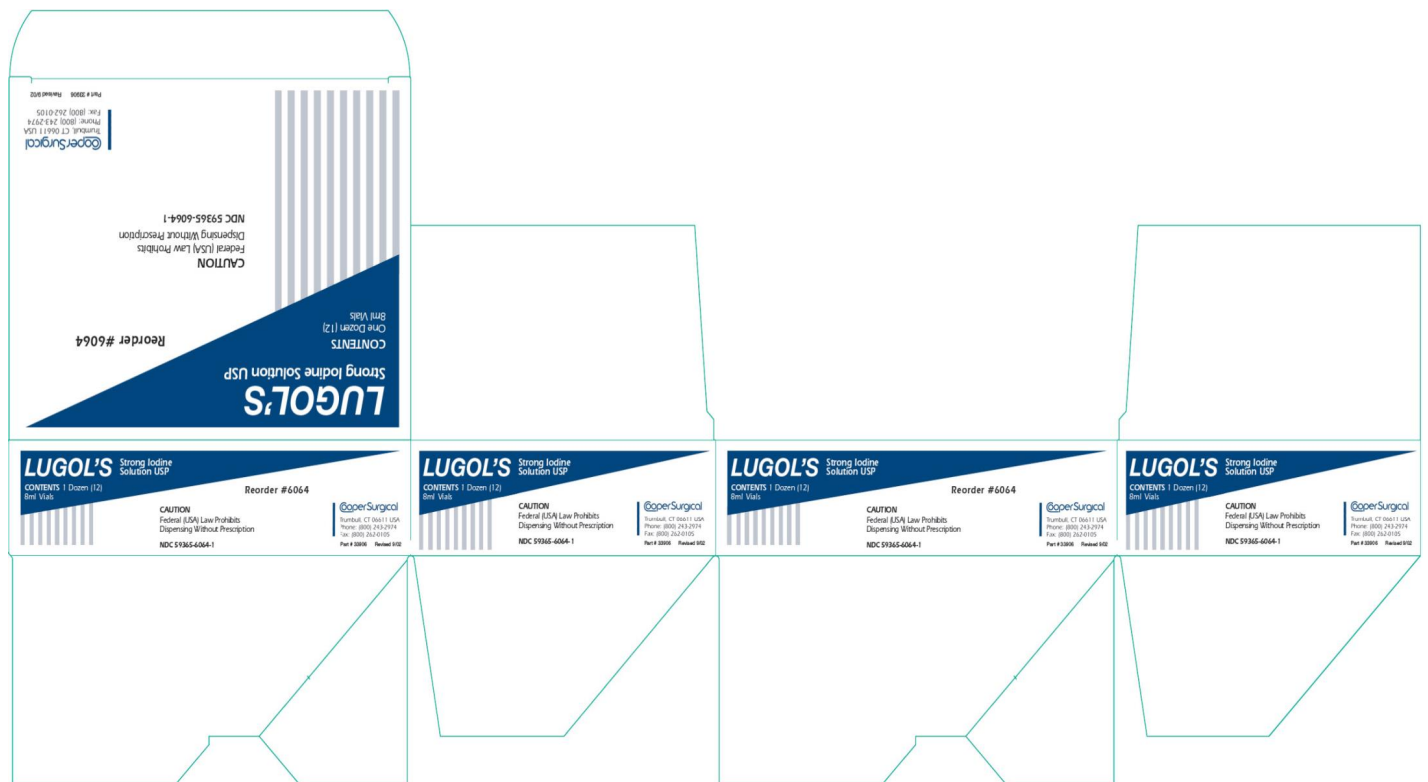
Keep tightly closed. Protect from light. **DO NOT** use if seal has been broken. Store at controlled room temperature 15°-30°C (59°-86°F).

DISPOSAL

Opened containers with unused portions of product and applicator swabs containing residual product should be placed in a suitable, dry container for disposal following local hazardous waste practices. Waste containing LUGOL'S should not be subjected to any thermal process whether intended for destruction or recycling purposes.

PRINCIPAL DISPLAY PANEL

Lugol's
Strong Iodine Solution USP
Contents
One Dozen (12)
8ml Vials



PRINCIPAL DISPLAY PANEL

8mL NDC 59365-6064-0
Lugol's
(STRONG IODINE SOLUTIONS USP)

8mL REF 6064 NDC 59365-6064-0

EACH mL CONTAINS:
 Iodine 0.05gm,
 Potassium iodide 0.100gm.

DOSE: SINGLE USE
 DO NOT REUSE, DISCARD AFTER USE, KEEP TIGHTLY CLOSED, PROTECT FROM LIGHT, DO NOT USE IF SEAL HAS BEEN BROKEN. STORE AT CONTROLLED ROOM TEMPERATURE 15°-30°C (59°-86°F).

Manufactured for CooperSurgical
 Trumbull, CT 06611 Rev. 08/2015

LUGOL'S
 (STRONG IODINE SOLUTION USP)

CooperSurgical

CAUTION: Federal law prohibits dispensing without prescription.

LOT NO.
EXP. DATE

LUGOLS STRONG IODINE

iodine and potassium iodide solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:59365-6064
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IODINE (UNII: 9679TC07X4) (IODINE - UNII:9679TC07X4)	IODINE	0.05 g in 1 mL
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	POTASSIUM IODIDE	0.100 g in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59365-6064-1	12 in 1 CARTON	10/01/1992	
1	NDC:59365-6064-0	8 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		10/01/1992	

Labeler - CooperSurgical, Inc. (801895244)