STRONG IODINE SOLUTION- strong iodine solution solution/ drops
Safecor Health, LLC

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.

NDC 48433-230-15
STRONG IODINE SOLUTION, U.S.P.
(Lugol's Solution)

FOR ORAL USE ONLY

DESCRIPTION

Iodine 5g, potassium iodide 10g, in enough purified water to make 100 ml.

INDICATIONS

Strong Iodine Solution, containing 5 percent of iodine and 10 percent of potassium iodide, is employed in the prophylaxis of simple and colloid goiters and in the treatment of exophthalmic goiter. It can be used alone as a preoperative preparation but is now most commonly used concomitantly with propylthiouracil and other antithyroid drugs. When used with these drugs, Strong Iodine Solution produces involution of the hyperplastic gland thus making a less triable and vascular gland for thyroidectomy. In addition, it has an additive antithyroid action that helps make the patient enthyroid faster than if the antithyroid drugs were used alone.

CONTRAINDICATIONS

The use of iodides may be contraindicated in patients with tuberculosis because it is believed they may cause a breakdown of healing lesions. The use of iodides is contraindicated in patients with iododerma, laryngeal edema, and swelling of salivary glands or increased salivation upon previous exposure to iodides. Strong Iodine Solution is ineffective in the treatment of postoperative thyroid crisis.

PRECAUTIONS

Iodine therapy does not completely control the manifestations of hyperthyroidism and after a variable period of time, the beneficial effects wear off. With continued administration of the drug, the hyperthyroidism may return in its initial intensity or become even more severe than it was at first. Measurements of the protein-bound iodine or of the uptake of radioiodine are rendered useless if iodine is given.

WARNINGS

Prolonged therapy may cause iodism. USE IN PREGNANCY: The drug readily crosses the placental barrier and may affect the fetus if used during pregnancy.

ADVERSE REACTIONS

Ingestion of large quantities of Strong Iodine Solution may cause abdominal pain, nausea, vomiting and diarrhea. Average doses may cause skin rash.

DOSAGE

Strong Iodine Solution is for oral use only. The usual dosage of Strong Iodine Solution is 2 to 6 drops (0.1 to 0.3 ml) three times daily taken in water after meals for two or three weeks prior to operation. In thyroid crisis the dosage is **1** ml three times a day.

HOW SUPPLIED

Bottles of 14 ml, amber glass with lined plastic closures. Accompanying each bottle is a glass dropper which should be used when the solution is ready to be dispensed to minimize any loss of free iodine through the bulb of the dropper.

STORAGE

Store at room temperature

R_x only

SAFECOR HEALTH, LLC
WOBURN, MA 01801

230-02
Rev 05/2019

———Principal Display Panel———

Do Not Use in Eyes

NDC 48433-230-15
Rx only

SAFECOR
HEALTH

Strong Iodine
Solution U.S.P.
(Lugol's Solution)

NET CONTENTS 14 mL

STRONG IODINE SOLUTION

strong iodine solution solution/ drops

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:48433-230
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
IODINE (UNII: 9679TC07X4) (IODINE - UNII:9679TC07X4)	IODINE	700 mg in 1 mL
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	IODIDE ION	1400 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:48433-230-15	14 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/20/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/20/2008	

Labeler - Safecor Health, LLC (828269675)

Establishment

Name	Address	ID/FEI	Business Operations
Safecor Health, LLC		078805287	manufacture(48433-230)

Revised: 1/2025 Safecor Health, LLC