

HUMCO STRONG IODINE- iodine and potassium iodide liquid
Humco Holding Group, 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.

HUMCO Strong Iodine Solution (Lugol's Solution)

Strong Iodine Solution

Active Ingredient

Iodine 5 %

Potassium iodide 10%

Purpose

Iodine supplement

CAUTION TO PHYSICIAN:

Read the following indications, Side Effects, Precautions and Contraindications as a reminder in evaluating each case for supplemental iodine.

Use

Source of Iodine

INDICATIONS: This product has several uses where iodine is indicated. This product may be used in the treatment of hyperthyroidism in the immediate preoperative period in preparation for thyroidectomy. It may be used alone, but more frequently is used after the hyperthyroidism is controlled by an antithyroid drug. It is given during the 10 days immediately prior to the operation. Optimal control of Hyperthyroidism is achieved if antithyroid drugs are first given alone. This product is also used in thyrotoxicosis crisis in conjunction with supportive measures to control fever and adequate fluid intake.

CONTRAINDICATIONS:

Iodine should not be given to cases of active Tuberculosis, or those known to be sensitive to iodine, and discontinued in cases later developing a sensitivity to the iodine therapy.

WARNINGS

WARNING: Large dosage may cause iodine poisoning.

FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION.

Keep out of the reach of children.

In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

Warnings

VESICATION AND DESQUAMATION MAY OCCUR IF ALLOWED TO POOL IN CONTACT WITH THE SKIN. EXCESS IODINE SHOULD BE REMOVED WITH ALCOHOL TO PREVENT "IODINE BURNS."

SIDE EFFECTS AND PRECAUTIONS:

Iodine therapy does not completely control the manifestations of hyperthyroidism in that after a variable period of time, the beneficial effects wear off. With continue administration of iodine, the hyperthyroidism may return in its initial intensity or may 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. Average dosage of iodine may cause skin rash. Iodine readily crosses the placental barrier and may affect the fetus. Prolonged therapy may cause iodism. The ingestion of large quantities of iodine may cause abdominal pain, nausea, vomiting and diarrhea.

FIRST AID INSTRUCTIONS FOR ACCIDENTAL EXPOSURE:

If in eyes: Immediately flush eyes with plenty of water for 15 minutes.

If on skin: Immediately wash skin with plenty of water for 15 minutes.

If swallowed: CALL A PHYSICIAN. Do not induce vomiting. If conscious, give water, milk, or milk of magnesia.

Directions:

DOSAGE: USUAL DOSE; 4-1/2 minims 3 times daily. Dilute with water or juice.

USUAL DOSE RANGE: 1-1/2 to 15 minims daily.

Other information

CAUTION: THIS CONTAINER IS NOT "CHILD PROOF" AND MUST NOT BE SOLD FOR USE IN OR AROUND THE HOME.

Inactive ingredient

Purified water

Contains: Iodine 5%, Potassium Iodide 10%, Purified Water.

Indication and Usage: This product can be used as an iodine supplement where iodine is indicated. This product may be used in the treatment of hyperthyroidism in the immediate preoperative period in preparation for thyroidectomy. It may be used alone, but more frequently is used after the hyperthyroidism is controlled by an antithyroid drug. It is given during the 10 days immediately prior to the operation. Optimal control of hyperthyroidism is achieved if antithyroid drugs are first given alone. This product is also used in thyrotoxicosis crisis in conjunction with supportive measures to control fever and adequate fluid intake.

Contraindications: Iodine should not be given to patients with active Tuberculosis or patients who have iodine sensitivity. If a patient develops iodine sensitivity in the process of an iodine therapy, discontinue use immediately.

Warnings and Precautions: VESICATION AND DESQUAMATION MAY OCCUR IF ALLOWED TO POOL IN CONTACT OF SKIN. REMOVE EXCESS IODINE WITH ALCOHOL TO PREVENT "IODINE BURNS".

Iodine can cross the placental barrier and may affect the fetus.

Keep out of reach of children.

Iodine therapy does not completely control the manifestations of hyperthyroidism as the beneficial effects wear off after a variable period of time.

Continued ▶

Manufactured by: Humco Holding Group, Inc.
7400 Alutraz Rd., Texarkana, TX 75501
Questions or Comments? (714) 800-662-3435

STRONG IODINE SOLUTION (LUGOL'S SOLUTION)



Quality Rx

USP

USED AS A SOURCE OF IODINE

RX Only

16 FL oz (1 pt) 473 mL

Warnings and Precautions (continued)

Even with continued administration of iodine, the hyperthyroidism may return in its initial intensity or may become more severe. Unless iodine is given, measurements of the protein-bound iodine or of the uptake of radioiodine are rendered useless.

Adverse Reactions: Ingestion of large quantities of iodine may cause abdominal pain, nausea, vomiting and diarrhea. Large dosage or prolonged iodine therapy may cause iodine poisoning/iodism. Average dosage may cause skin rash.

Overdosage: In case of accidental overdose, seek professional help or contact a Poison Control Center immediately (1-800-222-1222).

Usual Dosage: 0.28 mL three times a day. Usual dosage range: 0.09 mL to 0.92 mL daily.

Administration: Dilute with water or juice before ingestion.

Caution: Dispense in child-resistant and light-resistant containers.

First Aid Instructions for Accidental Exposure: If in eyes or on skin, immediately flush eyes or wash skin with running water for 15 minutes. If swallowed, immediately call a physician for professional help. Do not induce vomiting. If conscious, drink water, milk or Milk of Magnesia.

R092819



SERIAL# BARCODE HERE

HUMCO STRONG IODINE

iodine and potassium iodide liquid

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0395-2775
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IODINE (UNII: 9679TC07X4) (IODINE - UNII:9679TC07X4)	IODINE	50 mg in 1 mL
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	IODIDE ION	100 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:0395-	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a	11/14/2017	

2775-16	Combination Product	11/14/2017	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/2008	

Labeler - Humco Holding Group, Inc. (825672884)

Registrant - Pharma Nobis, LLC (118564114)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	manufacture(0395-2775) , analysis(0395-2775) , pack(0395-2775) , label(0395-2775)

Revised: 3/2022

Humco Holding Group, Inc.