SSKI- potassium iodide solution
ATLANTIC BIOLOGICALS CORP.

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.

SSKI®
Potassium Iodide Oral Solution, USP (Saturated)
1 g/mL

Rx only

Description

SSKI® (potassium iodide oral solution, USP) is a saturated solution of potassium iodide containing 1 gram of potassium iodide per mL.

Clinical Pharmacology

Potassium iodide is thought to act as an expectorant by increasing respiratory tract secretions and thereby decreasing the viscosity of mucus.

Indications and Usage

SSKI® (potassium iodide oral solution, USP) is for use as an expectorant in the symptomatic treatment of chronic pulmonary diseases where tenacious mucus complicates the problem, including bronchial asthma, bronchitis and pulmonary emphysema.

Contraindications

Contraindicated in patients with a known sensitivity to iodides.

Warnings

Potassium iodide can cause fetal harm, abnormal thyroid function, and goiter when administered to a pregnant woman. Because of the possible development of fetal goiter, if the drug is used during pregnancy or if the patient becomes pregnant during therapy, apprise the patient of the potential hazard.

Precautions

General

In some patients, prolonged use of iodides can lead to hypothyroidism. Iodides should be used with caution in patients having Addison's disease, cardiac disease,

hyperthyroidism, myotonia congenita, tuberculosis, acute bronchitis, or renal function impairment.

Drug Interactions

Concurrent use with lithium or antithyroid drugs may potentiate the hypothyroid and goitrogenic effects of these medications. Concurrent use with potassium-containing medications, potassium-sparing diuretics and angiotensin-converting enzyme inhibitors (ACE inhibitors) may result in hyperkalemia and cardiac arrhythmias or cardiac arrest.

Drug/Laboratory Test Interactions

Thyroid function tests may be altered by iodide.

Pregnancy

see "Warnings" section.

Nursing Mothers

Potassium iodide is excreted in breast milk. Use by nursing mothers may cause skin rash and thyroid suppression in the infant.

Pediatric Use

Safety and effectiveness in children have not been established.

Adverse Reactions

The most frequent adverse reactions to potassium iodide are stomach upset, diarrhea, nausea, vomiting, stomach pain, skin rash, and salivary gland swelling or tenderness. Less frequent adverse reactions include gastrointestinal bleeding, confusion, irregular heartbeat, numbness, tingling, pain or weakness in hands or feet, unusual tiredness, weakness or heaviness of legs, fever, and swelling of neck or throat. Thyroid adenoma, goiter, and myxedema are possible side effects.

Iodism or chronic iodine poisoning may occur during prolonged treatment or with the use of high doses. The symptoms of iodism include burning of mouth or throat, severe headache, metallic taste, soreness of teeth and gums, symptoms of head cold, irritation of the eyes with swelling of the eyelids, unusual increase in salivation, acneform skin lesions in the seborrheic areas, and rarely, severe skin eruptions. If symptoms of iodism appear, the drug should be withdrawn and the patient given appropriate supportive therapy.

Hypersensitivity to iodides may occur and may be manifested by angioedema, cutaneous and mucosal hemorrhage, and signs and symptoms resembling serum sickness, such as fever, arthralgia, lymph node enlargement, and eosinophilia.

Overdosage

Acute toxicity from potassium iodide is relatively rare. An occasional individual may show marked sensitivity and the onset of acute poisoning can occur immediately or hours after administration. Angioedema, laryngeal edema and cutaneous hemorrhages may

occur.

Iodism or chronic iodine poisoning may occur during prolonged treatment or with the use of high doses. Symptoms of iodism typically disappear soon after discontinuation of the drug. Abundant fluid and salt intake aids in iodide elimination.

Dosage and Administration

Adults

0.3 ml (300 mg) or 0.6 ml (600 mg) diluted in one glassful of water, fruit juice or milk 3 to 4 times daily. To minimize gastric irritation, take with food or milk.

This medication should be used no longer than necessary to produce the desired effect.

How Supplied

ndc 17856-0114-01 (potassium iodide oral solution, USP) is supplied in 0.1G/0.1mL 120 Syringes

bulk ndc 71740-0112-30

Inactive ingredient: Sodium thiosulfate as a preservative.

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Keep tightly closed and protected from light.

For the 237mL bottle, dispense in tight, light-resistant containers with child-resistant closures. For the 30mL bottle, place the child-resistant cap back on the amber glass bottle after using the clear plastic dropper for dispensing.

Notice: When exposed to cold temperatures, crystallization may occur, but on warming and shaking, the crystals will redissolve. If the solution turns brownish-yellow in color, it should be discarded.

DISTRIBUTED BY:

ATLANTIC BIOLOGICALS CORP.

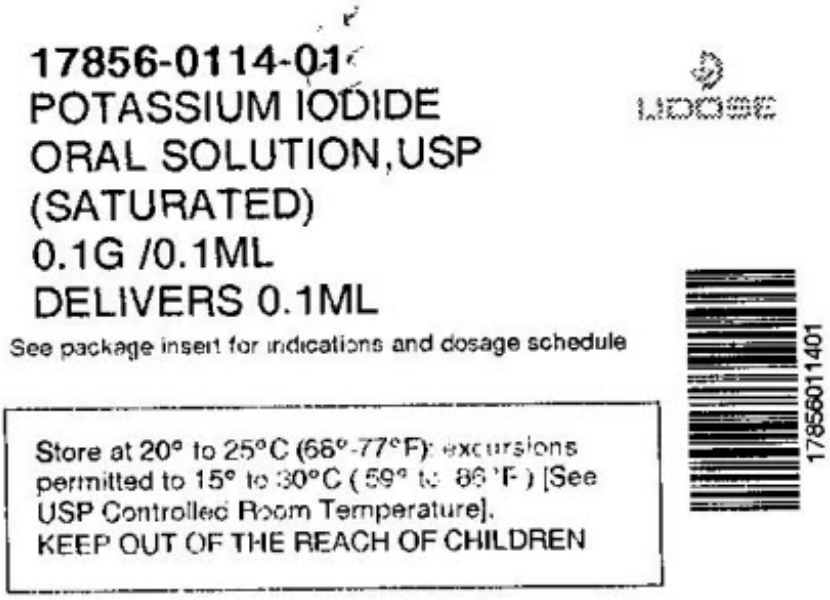
MIAMI, FL 33179

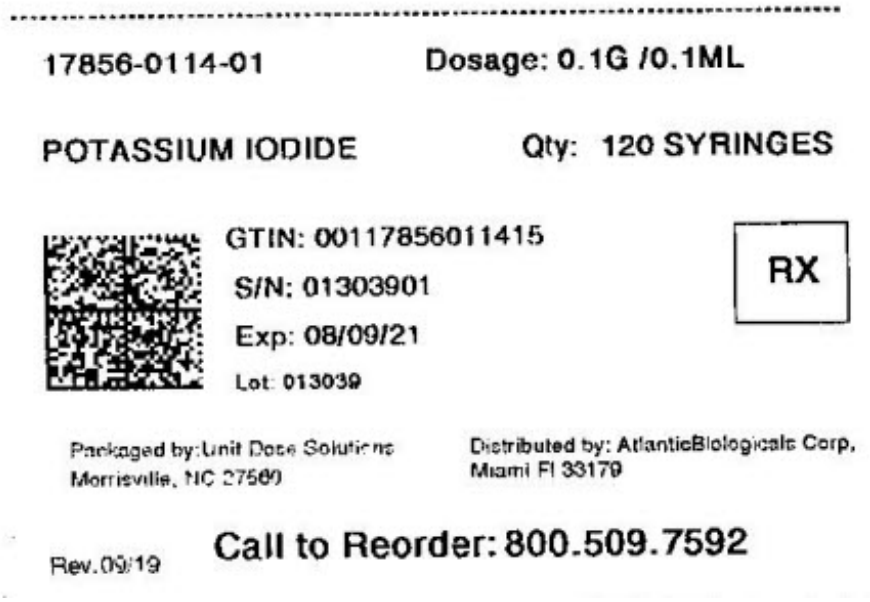
PRINCIPAL DISPLAY PANEL - 30 mL Bottle Label

NDC 17856-0114-1

Potassium Iodide
Oral Solution, USP
(saturated)

1 g/mL





SSKI

potassium iodide solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:17856-0114(NDC:71740-112)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Potassium Iodide (UNII: 1C4QK22F9J) (Iodide Ion - UNII:09G4I6V86Q)	Potassium Iodide	1 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
sodium thiosulfate (UNII: HX1032V43M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-0114-1	120 in 1 BOX, UNIT-DOSE	08/18/2023	
1	NDC:17856-0114-3	0.1 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:17856-0114-2	120 in 1 BOX, UNIT-DOSE	08/18/2023	
2	NDC:17856-0114-4	0.1 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		11/13/2017	

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment

Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	repack(17856-0114)

Revised: 8/2023 ATLANTIC BIOLOGICALS CORP.