

I 123 MINI - i 123 mini capsule
AnazaoHealth Corporation

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.

I-123 Mini Caps
Medical Professional Information Sheet

Dear Medical Professional, Per your order, we have compounded I-123 in Mini Cap form. The characteristics of this compound are:

DESCRIPTION

Sodium Iodide I-123 (NaI-123) for diagnostic use is supplied for oral administration in a small opaque white gelatin capsule, which is placed inside a red and clear outer capsule. The capsules are available in strengths up to 10 mCi of I-123 at a specific time. Gelatin capsules are compounded, per prescription requirements, using high specific concentration I-123, allowing higher iodine activity in a small easy to swallow capsule size. The radionuclidic composition at calibration is not less than 97.0 percent I-123, not more than 2.9 percent I-125 and not more than 0.1 percent Te-121. The radionuclidic composition at expiration time is not less than 87.2 percent I-123, not more than 12.4 percent I-125 and not more than 0.4 percent Te-121. The ratio of the concentration of I-123 and I-125 changes with time. Iodine-123 has a physical half-life of 13.2 hours.

INDICATIONS AND USAGE

Administration of Sodium Iodide I-123 is indicated as a diagnostic procedure to be used in evaluating thyroid function and/or morphology

DOSAGE AND ADMINISTRATION

Anti-thyroid therapy of a severely hyperthyroid patient is usually discontinued three to four days before administration of radioiodide. For hyperthyroidism, the usual dose range is 4 to 10 mCi. Toxic nodular goiter and other special situations will require the use of larger doses. For thyroid carcinoma, 50 mCi is the usual dose for ablation of normal thyroid tissue, and 100 to 150 mCi is the usual subsequent therapeutic dose. Waterproof gloves should be used during the entire handling and administration procedure. Adequate shielding must be maintained.

CLINICAL UTILITY

.Sodium Iodide I-123 is readily absorbed from the upper gastrointestinal tract. Following absorption, the iodide is distributed primarily within the extracellular fluid of the body. It is trapped and organically bound by the thyroid and concentrated by the stomach, choroid plexus and salivary glands. It is excreted by the kidneys. The fraction of the administered dose which is accumulated in the thyroid gland may be a measure of thyroid function in the absence of unusually high or low iodine intake or administration of certain drugs which influence iodine accumulation by the thyroid gland. Normal subjects can accumulate approximately 10 to 50% of the administered iodine dose in the thyroid gland, however, the normal and abnormal ranges are established by individual physician's criteria. The mapping (imaging) of Sodium Iodide I-123 distribution in the thyroid gland may provide useful information concerning thyroid anatomy and definition of normal and/or abnormal functioning of tissue within the gland

Thank you,

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

I-123 Mini Capsules for Thyroid Uptake

Sodium Phosphate Dibasic 100 mg

Dosage: Ranges from 100-999 microcuries

Lot#: Pharmacy Compounded **Exp:**



5710 Hoover Blvd., Tampa, FL 33634
Phone (800)995-4363 Fax (800)697-5250

I-123 Mini Capsules for Whole Body Scans

Sodium Phosphate Dibasic 100 mg

Dosage: Ranges from 1-10 millicuries

Lot#: Pharmacy Compounded **Exp:**



5710 Hoover Blvd., Tampa, FL 33634
Phone (800)995-4363 Fax (800)697-5250

I 123 MINI

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Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:51808-102
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IODIDE ION I-123 (UNII: 8 YWR746RPQ) (IODIDE ION I-123 - UNII:8 YWR746 RPQ)	IODIDE ION I-123	10 mCi

Inactive Ingredients

Ingredient Name	Strength
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	100 mg

Product Characteristics

Color	WHITE (one half opaque white and other half red)	Score	no score
Shape	CAPSULE	Size	3mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51808-102-01	2 in 1 VIAL		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		05/23/2012	

Labeler - AnazaoHealth Corporation (011038762)**Establishment**

Name	Address	ID/FEI	Business Operations
AnazaoHealth Corporation		011038762	MANUFACTURE(51808-102)

Revised: 5/2012

AnazaoHealth Corporation