I 131 MINI - i 131 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-131 Mini Caps
Medical Professional Information Sheet

Dear Medical Professional, Per your order, we have compounded I-131 in Mini Cap form. The characteristics of this compound are:

DESCRIPTION

Sodium Iodide I-131 (NaI-131) for therapeutic use is supplied for oral administration in small opaque white gelatin capsules, inside a blue and clear outer capsule. Each I-131 mini capsule is available in strengths ranging from (0.1 – 150 mCi) at the time of calibration. Iodine 131 decays by beta emission and associated gamma emission with a physical half-life of 8.04 days.

Sodium Iodide I-131 Mini Capsules are compounded by absorbing a solution of carrier-free sodium iodide I-131 into inert filler. The iodine 131 utilized in the preparation of the capsules contains not less than 99% Iodine-131 at the time of calibration.

Gelatin capsules are compounded per prescription requirements using high specific concentration I-131, allowing higher iodine activity in a small easy to swallow high activity capsule size. Capsules are formulated to rapidly dissolve in saline solution, to allow use for oral solution administration when clinically necessary.

CONTRAINDICATIONS AND ADVERSE REACTIONS

Radioiodine is excreted in human milk during lactation; breast feeding must be substituted during and following dose administration. Sodium Iodide 131 is not usually used for treatment of hyperthyroidism in patients under 30 years of age. Reactions to administration are rare; however potential side effects such as radiation sickness and bone marrow depression, acute leukemia, anemia, chromosomal abnormalities, acute thyroid crisis, blood dyscrasia, leukopenia, thrombocytopenia, and death represent potential side effects.

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

Most patients with thyroid disease present with a thyroid nodule. Tools utilized to assess thyroid nodules and to rule out thyroid cancer include: serum thyroid function tests (TSH and thyroid hormone level), thyroid ultrasound (US), radionuclide scintigraphy (low activity I-131, I-123 and/or Tc99m), and fine needle aspiration (FNA) for cytology (cells) examination. High thyroid hormone levels (T4 or T3)

and a low TSH level may indicate a nodule is a benign hyperfunctioning nodule (adenoma), thereby tending to rule out thyroid cancer. In such cases, thyroid imaging (US or scintigraphy) determines whether the nodule is hyperfunctioning whereas thyroid cancers appear under-functioning or "cold" on the scan. Graves' disease and Hashimotos' thyroiditis represent thyroid diseases which occur in children who have autoimmune thyroid disease. In these patients, abnormal thyroid function tests reflect underlying thyroid disease but do not exclude thyroid cancer.

The administration of radioiodine has proved to be an excellent method of destruction of over functioning thyroid tissue (either diffuse or toxic nodular goiter). Radioiodine is concentrated in the thyroid, destroying cells that concentrate it.

Surgical removal is the treatment of choice for thyroid carcinomas. At 2 to 4 months post surgery, a whole-body I-131 scan is performed following cessation of thyroxin drug for 4-6 weeks prior to the scan, thereby causing hypothyroidism; TSH then rises and stimulates iodide uptake. Iodine-containing foods and contrast media are avoided. Patients with significant I-131 uptake are given ablative (100 - 150 mCi) doses of I-131. For minimal uptake, doses of 30-50 mCi I-131 are given on an outpatient basis. Patients with extra thyroidal uptake from metastatic disease may be given larger doses of greater than 100 mCi.

I-131 THERAPY CAPSULE MARKET BACKGROUND

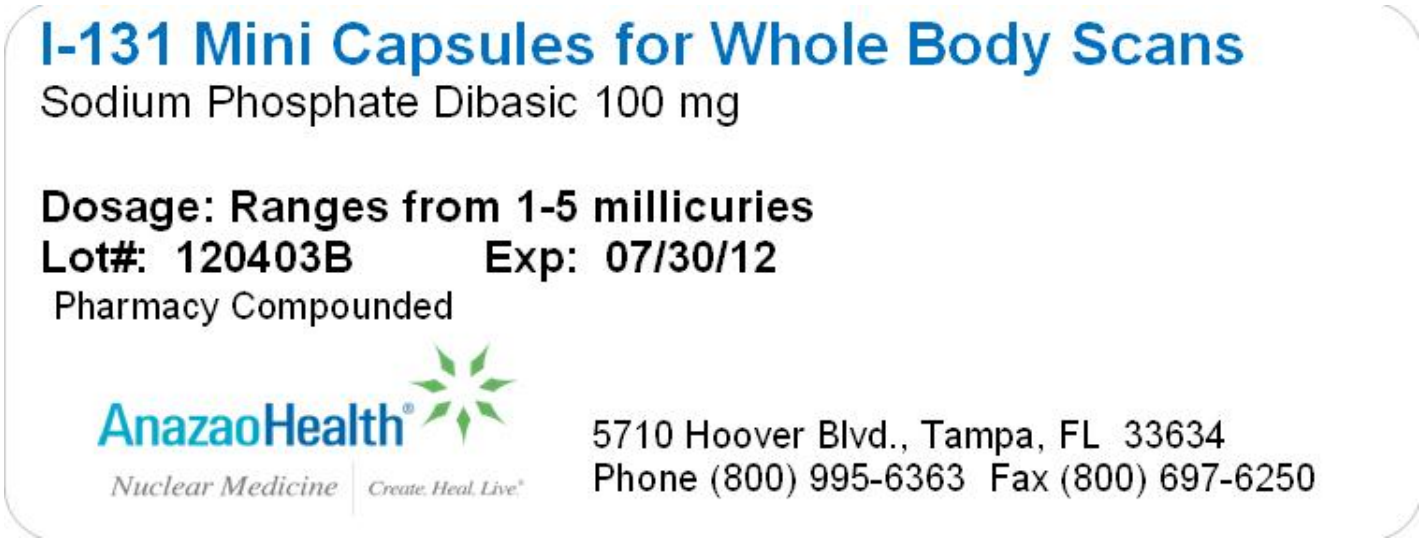
I-131 Therapy Capsule formulations provide an enhanced safety profile for nuclear medicine professionals. Oral solutions raise the risk for spills during administration in addition to the not uncommon scenario where very ill patients reject oral solution treatment; whereupon vomiting episodes create large areas of high level radiation spill. Oral solutions, however, are sold at deep discounts as compared to Therapy Capsules.

While many U.S. facilities have moved to adopt ALARA recommendations to reduce radiation exposure to healthcare workers which reasonably include routinely ordering encapsulated high activity I-131; the scenario also exists that the intended patient may not be able to swallow the Therapy Capsule for reasons including: the large size of competitive suppliers, as well as intubated, quadriplegia and/or severe swallowing difficulties. In these instances, it is particularly beneficial to have the ability to dissolve the capsule so that the patient may be treated on the same day, without having to order additional preparation.

Thank you,

AnazaoHealth Corporation

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



I-131 Mini Capsules for Thyroid Therapy

Sodium Phosphate Dibasic 100 mg

Dosage: Ranges from 6-500 millicuries

Lot#: 120403B Exp: 07/30/12

Pharmacy Compounded

AnazaoHealth®
Nuclear Medicine | Create. Heal. Live.®

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Phone (800) 995-6363 Fax (800) 697-6250

I 131 MINI

i 131 mini capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51808-119
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM IODIDE I-131 (UNII: 29VCO8ACHH) (IODIDE I-131 - UNII:I5X6L61HUT)	SODIUM IODIDE I-131	500 mCi

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

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51808-119-01	3 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

Revised: 5/2012 AnazaoHealth Corporation