The specific gamma-ray constant for iodine I-131 is 0.89 $10^{-1}$ hr$^{-1}$ (2.27 R/mCi-hr) at 1 cm. The first half-life of iodine I-131 is 8.05 days (186 hr), followed by a decay period of about 50 years, during which time it is converted to stable iodine. Iodine I-131 is the most active of the iodine isotopes used for diagnostic purposes, and it is used in a variety of nuclear medicine procedures.

The radioactive iodine is incorporated so rapidly that the iodide trap of the thyroid contains about 50 times the normal level of iodine. The iodide is then taken up by the thyroid gland, converted to thyroglobulin, and stored for future release.

The thyroid gland is responsible for the production of two hormones, thyroxine (T4) and triiodothyronine (T3), which are essential for the normal functioning of the body. These hormones are synthesized from iodine and released into the bloodstream, where they are transported by plasma thyroid binding proteins. These reaction products of thyroglobulin into the blood where they are specifically bound to plasma proteins. These proteins transport the hormones to other tissues where they act to regulate metabolism.

Thyroid nodules are formed in the thyroid gland, and these nodules may contain abnormal amounts of iodine. The iodine in these nodules is taken up by the thyroid cells, where it is used to produce thyroid hormones. The presence of these nodules can be detected using nuclear medicine procedures, and the results can be used to diagnose and treat thyroid disorders.

The concentration of iodine in the thyroid gland is a function of the amount of iodine in the diet and the amount of iodine that is excreted in the urine. The amount of iodine in the diet can be increased by consuming foods that are rich in iodine, such as seafood, leafy greens, and cruciferous vegetables. The amount of iodine that is excreted in the urine can be reduced by limiting the intake of iodine-rich foods, such as dairy products and processed foods.

The concentration of iodine in the thyroid gland is also affected by the amount of thyroid hormone that is produced. The production of thyroid hormone is regulated by the hypothalamus, which releases thyroid-stimulating hormone (TSH) to stimulate the thyroid gland. TSH stimulates the production of thyroid hormones, which are then released into the bloodstream. The thyroid hormones act on other tissues in the body, where they regulate metabolism.

The concentration of iodine in the thyroid gland is also affected by the amount of iodine that is excreted in the urine. The amount of iodine that is excreted in the urine can be reduced by limiting the intake of iodine-rich foods, such as dairy products and processed foods. The amount of iodine that is excreted in the urine can also be increased by consuming foods that are rich in iodine, such as seafood, leafy greens, and cruciferous vegetables.

The concentration of iodine in the thyroid gland is also affected by the amount of iodine that is absorbed by the body. The amount of iodine that is absorbed by the body can be increased by consuming foods that are rich in iodine, such as seafood, leafy greens, and cruciferous vegetables. The amount of iodine that is absorbed by the body can also be reduced by limiting the intake of iodine-rich foods, such as dairy products and processed foods.

The concentration of iodine in the thyroid gland is also affected by the amount of iodine that is stored in the body. The amount of iodine that is stored in the body can be increased by consuming foods that are rich in iodine, such as seafood, leafy greens, and cruciferous vegetables. The amount of iodine that is stored in the body can also be reduced by limiting the intake of iodine-rich foods, such as dairy products and processed foods.
DOSAGE AND ADMINISTRATION

The concentrated Sodium Iodide I-131 Solution USP provided with HICON® must not be used for direct administration to patients. It must be diluted as described in the DRUG HANDLING AND FINAL DOSAGE FORM PREPARATION section.

The recommended dosage for orally administered Sodium Iodide I-131 Solution USP is based on the thyroid gland uptake as determined by the physician prior to treatment and may be useful in calculating the therapeutic dose to be administered to the individual patient. Recommended doses of orally administered Sodium Iodide I-131 are:

**Absorbed Radiation Doses I-131**

<table>
<thead>
<tr>
<th>Tissue</th>
<th>Absorbed Radiation Dose (mSv)</th>
<th>Absorbed Radiation Dose (mSv/MBq)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thyroid</td>
<td>350,000</td>
<td>96</td>
</tr>
<tr>
<td>Testes</td>
<td>150</td>
<td>4.3</td>
</tr>
<tr>
<td>Ovaries</td>
<td>150</td>
<td>4.3</td>
</tr>
<tr>
<td>Whole body</td>
<td>100</td>
<td>2.8</td>
</tr>
</tbody>
</table>

Method of Calculation: A Scheme for Absorbed-Dose Calculations for Standardized Therapeutic Oral Doses of Iodine-131. The recommended dose should be calculated under the following assumptions:

1. The concentration of Sodium Iodide I-131 Solution USP provided with HICON® should not be used after the expiration date stated on the container label.
2. The solution should be inspected visually for particulate matter and discoloration prior to direct administration whichever solution and container permit. The solution should not be used if cloudy, discolored, or found to contain particulate matter. However, it is well known that glass lenses darken in the presence of high radioactivity.
3. Care should be taken to minimize radiation exposure to the patient consistent with proper patient management and to insure minimal radiation exposure to occupational workers.

Waterproof gloves should be used during the entire handling and administration procedure. Adequate shielding should be maintained during the life of the product.

Preparation of Oral Sodium Iodide I-131 Solution USP

1. Using the calibration date and radionuclidic concentration on the label of the product, calculate the required volume to produce the necessary dose in MBq or mCi.
2. Using a calibrated syringe, remove the required volume.
3. Using the syringed syringe, transfer the required volume to a suitably shielded receiving vid.
4. Add diluent solution to the receiving vial to produce a final dose of the desired volume. The recommended diluent is Purified Water USP containing 0.2% Sodium Thiosulfate USP as a reducing agent. The use of acidic diluents may cause the pH of the product to fall below 5 and stimulate the volatilization of Iodine-131.
5. The patient dose should be measured by a suitable radiotracer calibration system immediately prior to administration.
6. The finished preparation should not be used after the expiration date stated on the container label.

Preparation of Sodium Iodide I-131 Capsules USP

The Sodium Iodide I-131 Capsules USP are designed to be swallowed whole prior to administration. Absorption of the radiopharmaceutical from the capsule is not expected.

**DRUG HANDLING AND FINAL DOSAGE FORM PREPARATION**

Drug Handling

1. The concentrated Sodium Iodide I-131 Solution USP provided with HICON® should not be used for direct administration to patients. It must be diluted as described in the DRUG HANDLING AND FINAL DOSAGE FORM PREPARATION section.

Final Dosage Form Preparation

Method of Calculation: A Scheme for Absorbed-Dose Calculations for Standardized Therapeutic Oral Doses of Iodine-131. The recommended dose should be calculated under the following assumptions:

1. The concentration of Sodium Iodide I-131 Solution USP provided with HICON® should not be used after the expiration date stated on the container label.
2. The solution should be inspected visually for particulate matter and discoloration prior to direct administration whichever solution and container permit. The solution should not be used if cloudy, discolored, or found to contain particulate matter. However, it is well known that glass lenses darken in the presence of high radioactivity.

1. With an appropriate syringe, withdraw the required volume of Sodium Iodide I-131 Solution USP (maximum 150 mL) from the vial as illustrated below.

2. After dispensing, the patient dose should be measured in a suitable radiotracer calibration system immediately prior to administration.

3. Store the capsule in a suitable polyethylene container and place inside a lead pot until used. The capsule should be used within seven days.

4. Insert an unopened SMALL capsule into the bottom half of the empty large capsule as illustrated below.

5. Slip the upper half of the large capsule over the bottom half to completely cover the small capsule and push down gently until locked as illustrated below.

6. Inject into the center of the SMALL capsule through the top as illustrated below.

7. With a appropriate syringe, withdraw the required volume of Sodium Iodide I-131 Solution USP (maximum 150 mL) from the vial as illustrated below.

8. After dispensing, the patient dose should be measured in a suitable radiotracer calibration system immediately prior to administration.

9. Store the capsule in a suitable polyethylene container and place inside a lead pot until used. The capsule should be used within seven days.

10. Use with a new dosage form to avoid the need for individual dosage calculation.

**HOW SUPPLIED**

Each HICON® kit of 9.25 GBq to 37 GBq (250 mCi to 1,000 mCi) includes:

- a minimum of one blister package of ten small hard gelatin capsules each containing approximately 300 mg of Dibasic Sodium Phosphate Anhydrous USP as an absorbing buffer.
- a maximum of one blister package of ten empty large hard gelatin capsules.
- A 1 mL vial containing 0.25 mL to 1 mL of Sodium Iodide I-131 Solution USP, therapeutic oral solution containing approximately 9.25 GBq to 37 GBq (250 mCi to 1,000 mCi) at time of calibration.

Each of the aqueous product that comes with HICON® contains 37 GBq capsules of Sodium Iodide I-131 - 2.4 ± 0.25 mg of Oxidized Chitosan Oligomers, 0.2 ± 0.05 mg of Sodium Thiosulfate Pentahydrate USP, and 43 ± 2.5 mg of Dibasic Sodium Phosphate Anhydrous USP. Complete assay data are available on the container.

**STORAGE**

The Sodium Iodide I-131 Solution USP provided with HICON® should be stored between 2°C and 25°C (37°F and 77°F).

NDC: 65174-880-25 (250 mCi vial size)
NDC: 65174-880-50 (500 mCi vial size)
NDC: 65174-880-75 (1,000 mCi vial size)

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