GE Healthcare

**PACKAGE LEAFLET:**
**INFORMATION FOR THE**
**HEALTHCARE PROFESSIONAL**

**THERACAP$^{131}$TM**
**37 MBq-5.55 GBq**
**capsules, hard**

Sodium [$^{131}$I] iodide
**IBS600P**

## 1. NAME OF THE MEDICINAL PRODUCT

THERACAP$^{131}$ TM
37 MBq-5.55 GBq capsules, hard

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

THERACAP is presented as a single yellow capsule containing sodium [$^{131}$I] iodide in the following dosage range; 37-740 MBq in 37 MBq steps, 50 – 1000 MBq in 50 MBq steps, 0.925-5.55 GBq in 185 MBQ steps and 1000 – 5500 MBq in 100 MBq steps at the activity reference date. Each capsule contains a maximum of 20 µg of sodium iodide. The specific activity of the sodium [$^{131}$I] iodide is not less than 222 GBq/mg.

Iodine-131 is produced by fission of uranium-235 or by neutron bombardment of stable tellurium in a nuclear reactor. Iodine-131 has a half life of 8.02 days. It decays by emission of gamma radiations of 365 keV (81.7%), 637 keV (7.2%) and 284 keV (6.1%) and beta radiations of maximal energy of 606 keV to stable xenon-131.

This medicinal product contains: not more than 1.9 mmol (44 mg) of sodium per capsule.
For a full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Capsule, hard.
Yellow gelatin capsule.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Radioiodine thyroid therapy is indicated for:

- Treatment of Graves' disease, toxic multinodular goitre or autonomous nodules.
- Treatment of papillary and follicular thyroid carcinoma including metastatic disease.

Sodium [131I] iodide therapy is often combined with surgical intervention and with antithyroid medications.

**4.2 Posology and method of administration**

The activity administered is a matter for clinical judgement. The therapeutic effect is only achieved after several months.

- For the treatment of hyperthyroidism

The activity administered is usually in the range of 200-800 MBq but repeated treatment may be necessary. The dose required depends on the diagnosis, the size of the gland, thyroid uptake and iodine clearance. Patients should be rendered euthyroid medically whenever possible before giving radioiodine treatment for hyperthyroidism.

- For thyroid ablation and treatment of metastases

The administered activities following total or sub total thyroidectomy to ablate remaining thyroid tissue are in the range of 1850-3700 MBq. It depends on the remnant size and radioiodine uptake. In subsequent treatment for metastases, administered activity is in the range 3700-11100 MBq.

The activity to be administered in children and adolescents should be a fraction of the adult dose calculated from the body weight/surface area methods according to the following equation.

$$\text{Paediatric dose (MBq)} = \frac{\text{Adult dose (MBq)} \times \text{child weight (kg)}}{70 \text{ kg}}$$

$$\text{Paediatric dose (MBq)} = \frac{\text{Adult dose (MBq)} \times \text{child surface } (m^2)}{1.73 \ m^2}$$

Correction factors given for guidance are proposed below.

| **Fraction of adult dose** | | |
|---|---|---|
| 3Kg = 0.10 | 22Kg = 0.50 | 42Kg = 0.78 |
| 4Kg = 0.14 | 24Kg = 0.53 | 44Kg = 0.80 |
| 6Kg = 0.19 | 26Kg = 0.56 | 46Kg = 0.82 |
| 8Kg = 0.23 | 28Kg = 0.58 | 48Kg = 0.85 |
| 10Kg = 0.27 | 30Kg = 0.62 | 50Kg = 0.88 |
| 12Kg = 0.32 | 32Kg = 0.65 | 52-54Kg = 0.90 |
| 14Kg = 0.36 | 34Kg = 0.68 | 56-58Kg = 0.92 |
| 16Kg = 0.40 | 36Kg = 0.71 | 60-62Kg = 0.96 |
| 18Kg = 0.44 | 38Kg = 0.73 | 64-66Kg = 0.98 |
| 20Kg = 0.46 | 40Kg = 0.76 | 68Kg = 0.99 |

(Paediatric Task Group, European Association of Nuclear Medicines (EANM))

The capsule is administered orally together with a drink. It should be swallowed whole.

In patients with suspected gastrointestinal disease, great care should be taken when administering sodium [$^{131}$I] iodide capsules. The capsules should be swallowed whole with sufficient fluid to ensure clear passage into the stomach and upper small intestine. Concomitant use of $H_2$ antagonists or proton pump inhibitors is advised.

After high doses used e.g. for the treatment of thyroid carcinoma, patients should be encouraged to increase oral fluids to have frequent bladder emptying to reduce bladder radiation.

**4.3 Contraindications**

- Hypersensitivity to the active substance or to any of the excipients
- Pregnancy.
- For diagnostic purposes in children under 10 years of age.
- Thyroid scanning except in the follow-up of malignant disease or when iodine-123 or technetium-99m is not available.
- Patients with dysphagia, oesophageal stricture, active gastritis, gastric erosions and peptic ulcer.
- Patients with suspected reduced gastrointestinal motility.

**4.4 Special warnings and special precautions for use**

The possibility of hypersensitivity including anaphylactic / anaphylactoid reactions should always be considered. Advanced life support facilities should be readily available.

For radioprotection reasons following therapeutic doses, it is recommended to avoid close contact between mother and child for at least one week.

The risk of second primary malignancies in thyroid cancer survivors treated with radioactive iodine is slightly increased compared to thyroid cancer survivors not treated with radioiodine.

This medicinal product contains not more than 1.9 mmol (44 mg) of sodium in each capsule. To be taken into consideration by patients on a controlled sodium diet.

The administration of high dose radioiodine may result in significant environmental hazard. Suitable precautions should be taken concerning the activity eliminated by the patients in order to avoid any contamination.

The therapeutic administration of sodium [$^{131}$I] iodide in patients with significant renal impairment requires special attention with regards to administered activity.

There is inconclusive evidence of a beneficial effect of saliva stimulation to avoid sialadenitis.

A low-iodine diet prior to therapy will enhance uptake into functioning thyroid tissue. Thyroid replacement therapy should be stopped prior to radioiodine administration for thyroid carcinoma to ensure adequate uptake.

Hyponatraemia: Serious manifestations of hyponatraemia have been reported after sodium iodide [131I] therapy in elderly patients who have undergone total thyroidectomy. Risk factors include older age, female sex, use of thiazide diuretics and hyponatraemia at the start of sodium iodide [131I] therapy. Regular serum electrolytes measurements shall be considered for these patients.

Sperm banking should be considered for young men who have extensive disease and therefore may need high radioiodine therapeutic doses.

Contraception for 6 months (for patients with benign thyroid conditions) or 12 months (for patients with thyroid cancer) is recommended for both sexes after therapeutic administration of sodium [$^{131}$I] iodide.

For each patient, exposure to ionising radiation must be justifiable on the basis of likely benefit. The activity administered must be such that the resulting radiation dose is as low as reasonable achievable bearing in mind the need to obtain the intended diagnostic or therapeutic result.

**4.5 Interaction with other medicinal products and other forms of interaction**

A full drug history should be taken and relevant medication including the ones mentioned below should be withheld prior to the administration of sodium [$^{131}$I] iodide.

| **Active substances** | **Withdrawal period prior to administration of sodium [$^{131}$I] iodine.** |
|---|---|
| Antithyroid agents (e.g. carbimazole, methimazole, propyluracil), perchlorate | 2 – 5 days before until several days after administration. |
| Salicylates, steroids, sodium nitroprusside, sodium sulfobromophthalein, anticoagulants, antihistamines, antiparasitics, penicillins, sulphonamides, tolbutamide, thiopental | 1 week. |
| Phenylbutazone | 1-2 weeks. |
| Containing iodine expectorants and vitamins | approx. 2 weeks. |
| Thyroid hormone preparations | 2-6 weeks. |
| Amiodarone*, benzodia-zepines, lithium | approx. 4 weeks. |
| Containing iodine preparations for topical use | 1–9 months. |
| Water-soluble iodine-containing contrast media | up to 3 months . |
| Oral cholecystographic agents | for a period of up to 1 year. |

* Due to the long half-life of amiodarone, iodine uptake in the thyroid tissue can be decreased for several months.

**4.6 Fertility, pregnancy and lactation**

Pregnancy

Sodium [$^{131}$I] iodide is contraindicated during established or suspected pregnancy or when pregnancy has not been excluded. The absorbed dose to the uterus for this agent is likely to be in the range 11-511 mGy, and the foetal thyroid gland avidly concentrates iodine during the second and third trimesters. When it is necessary to administer radioactive products to women of childbearing potential, information should always be sought about pregnancy. Any woman who has missed a period should be assumed to be pregnant until proven otherwise.

Alternative techniques which do not involve ionising radiation should be considered. In the case of differentiated thyroid carcinoma diagnosed in pregnancy therefore, radioiodine treatment should be

postponed until after the pregnancy has ended. Women receiving sodium [$^{131}$I] iodide should be advised not to become pregnant within 6-12 months of administration.

Breastfeeding

Breastfeeding should be discontinued after sodium [$^{131}$I] iodide administration.

**4.7 Effects on ability to drive and use machines**

No studies on the effect on the ability to drive or use machines have been performed.

**4.8 Undesirable Effects**

The following undesirable effects are recognised for sodium [$^{131}$I] iodide:

The frequencies of undesirable effects are defined as follows:
Very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000) and not known (cannot be estimated from the available data).

<u>Blood and the lymphatic system disorders</u>

Not known: Bone marrow depression, including serious thrombcytopenia, erythrocytopenia and/or leukopenia

<u>Eye disorders</u>

Common: Sicca syndrome, endocrine ophthalmopathy

Not known: acquired dacryostenosis

<u>Gastrointestinal disorders</u>

Very common: Transient or persistent sialadenitis, including dry mouth, Nausea, vomiting Endocrine disorders

<u>Endocrine disorders</u>

Very common: Hypothyroidism

Not known: Aggravated hyperthyroidism, Basedow's (Graves') disease, hypoparathyroidism, hyperparathyroidism

<u>Neoplasms benign, malignant and unspecified (including cysts and polyps)</u>

Uncommon: leukaemia

Not known: Gastric cancer, bladder and breast cancer

<u>Immune system disorders</u>

Not known: Hypersensitivity

<u>Injury, poisoning and procedural complications</u>

Very common: Radiation injury, including radiation thyroiditis, radiation associated pain, tracheal obstruction

<u>Reproductive system and breast disorders</u>

Not known: Impairment of fertility in man and woman

Congenital, familial and genetic disorders

Not known: Congenital thyroid disorders

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form
http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il
and emailed to the Registration Holder's Patient Safety Unit at: drugsafety@neopharmgroup.com

**4.9 Overdose**

High radiation exposure through overdose can be reduced by means of administration of thyroid blocking agent, such as potassium perchlorate, the use of emetics and promoting a diuresis with frequent voiding of urine.

## 5. PHARMACOLOGICAL PROPERTIES

**5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: therapeutic radiopharmaceuticals, sodium [$^{131}$I] iodine, ATC Code: V10XA01
Iodide, in the amount used for therapeutic indications, is not known to have any pharmacological effect. More than 90 % of the radiation effects result from beta radiation which has a mean range of 0.5 mm.

**5.2 Pharmacokinetic properties**

After oral administration, sodium [$^{131}$I] iodide is absorbed rapidly from the upper gastrointestinal tract (90 % in 60 minutes). The pharmacokinetics follow that of un -labelled iodide. From the extra thyroidal compartment it is predominantly taken up by the thyroid or excreted renally. Small amounts of sodium [$^{131}$I] iodide are taken up by salivary glands, gastric mucosa and would also be localised in breast milk, the placenta and choroids plexus.

The effective half-life of radioiodine in plasma is in the order of 12 hours whereas that for radioiodine taken by the thyroid gland is about 6 days. Thus, after administration of sodium [$^{131}$I] iodide, approximately 40% of the activity has an effective half life of 0.4 days and the remaining 60%, 8 days. Urinary excretion is 37-75%, faecal excretion is about 10% with almost negligible excretion in sweat.

**5.3 Preclinical safety data**

No acute toxicity is expected or observed.
There are no data available on the toxicity of repeated doses of sodium iodide nor on its effects on reproduction in animals or its mutagenic or carcinogenic potential.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Sodium thiosulphate, pentahydrate
Disodium phosphate anhydrous
Sodium hydroxide
Silica, colloidal anhydrous
Maize starch
Water for injections
Capsule: Gelatin
Yellow iron oxide (E172)
Titanium dioxide (E171)
Sodium laurilsulfate
Acetic acid

### 6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

### 6.3 Shelf Life

The shelf life for this product is 14 days from the activity reference date stated on the label.

### 6.4 Special precautions for storage

Store below 25°C. Do not freeze.
Store in the original lead container or in equivalent shielding

### 6.5 Nature and contents of container

Each capsule is contained within a polycarbonate cup with a charcoal disc to absorb iodine-131. This cup is enclosed within a lead shield.

Pack sizes: 37-740 MBq in 37 MBq steps, 50 – 1000 MBq in 50 MBq steps, 0.925-5.55 GBq in 185 MBq steps and 1000 – 5500 MBq in 100 MBq steps. Each pack contains a single capsule.
Not all pack sizes may be marketed.

### 6.6 Special precautions for disposal

Normal safety precautions for handling radioactive materials should be observed. After use, all materials associated with the preparation and administration of radiopharmaceuticals, including any unused product and its container, should be decontaminated or treated as radioactive waste and disposed of in accordance with the conditions specified by the local competent authority. Contaminated material must be disposed of as radioactive waste via an authorised route.

## 7 DOSIMETRY

The ICRP model refers to intravenous administration. Since absorption of radioiodide is rapid and complete, this model is applicable in case of oral administration also but there is a further radiation dose to the stomach wall in addition to that due to gastric and salivary excretion. Assuming that the mean residence time in the stomach is 0.5 hr, the absorbed dose to the stomach wall increase by about 30 % for iodine-131.

Radiation dose to specific organs, which may not be the target organ of therapy can be influenced significantly by pathophysiological changes induced by the disease process.

As part of the risk-benefit assessment it is advised that the effective dose equivalent (EDE) and likely radiation doses to individual target organ(s) be calculated prior to administration. The activity might then be adjusted according to thyroid mass, biological half-life and the "re-cycling" factor which takes into account the physiological status of the patient (including iodine depletion) and the underlying pathology.

The tables below show the dosimetry as calculated according to the Publication 53 of the ICRP (International Commission on Radiological Protection, Radiation Dose to Patients from Radiopharmaceuticals, Pergamon Press 1987).

Iodide ($^{131}$I; 8.02 days)
Thyroid blocked uptake 0%

| **Organ** | **Absorbed dose per unit activity administered (mGy/MBq)** | | | | |
|---|---|---|---|---|---|
| | **Adult** | **15 years** | **10 years** | **5 years** | **1 year** |
| Adrenals | 3.7E-02 | 4.2E-02 | 6.7E-02 | 1.1E-01 | 2.0E-01 |
| Bladder wall | 6.1E-01 | 7.5E-01 | 1.1E+00 | 1.8E+00 | 3.4E+00 |
| Bone surfaces | 3.2E-02 | 3.8E-02 | 6.1E-02 | 9.7E-02 | 1.9E-01 |
| Breast | 3.3E-02 | 3.3E-02 | 5.2E-02 | 8.5E-02 | 1.7E-01 |
| GI tract | | | | | |
| Stomach wall | 3.4E-02 | 4.0E-02 | 6.4E-02 | 1.0E-01 | 1.9E-01 |
| Small intest | 3.8E-02 | 4.7E-02 | 7.5E-01 | 1.2E-01 | 2.2E-01 |
| ULI wall | 3.7E-02 | 4.5E-02 | 7.0E-02 | 1.2E-01 | 2.1E-01 |
| LLI wall | 4.3E-02 | 5.2E-02 | 8.2E-02 | 1.3E-01 | 2.3E-01 |
| Kidneys | 6.5E-02 | 8.0E-02 | 1.2E-01 | 1.7E-01 | 3.1E-01 |
| Liver | 3.3E-02 | 4.0E-02 | 6.5E-02 | 1.0E-01 | 2.0E-01 |
| Lungs | 3.1E-02 | 3.8E-02 | 6.0E-02 | 9.6E-02 | 1.9E-01 |
| Ovaries | 4.2E-02 | 5.4E-02 | 8.4E-02 | 1.3E-01 | 2.4E-01 |
| Pancreas | 3.5E-02 | 4.3E-02 | 6.9E-02 | 1.1E-01 | 2.1E-01 |
| Red marrow | 3.5E-02 | 4.2E-02 | 6.5E-02 | 1.0E-01 | 1.9E-01 |
| Spleen | 3.4E-02 | 4.0E-02 | 6.5E-02 | 1.0E-01 | 2.0E-01 |
| Testes | 3.7E-02 | 4.5E-02 | 7.5E-02 | 1.2E-01 | 2.3E-01 |
| Thyroid | 2.9E-02 | 3.8E-02 | 6.3E-02 | 1.0E-01 | 2.0E-01 |
| Uterus | 5.4E-02 | 6.7E-02 | 1.1E-01 | 1.7E-01 | 3.0E-01 |
| Other tissue | 3.2E-02 | 3.9E-02 | 6.2E-02 | 1.0E-01 | 1.9E-01 |
| **Effective dose equivalent (mSv/MBq)** | **7.2E-02** | **8.8E-02** | **1.4E-01** | **2.1E-01** | **4.0E-01** |

Bladder wall contributes to 50.8% of the effective dose equivalent.

The effective dose equivalent to an adult administered 5.55GBq with 0% thyroid uptake is 399.6 mSv.

**Incomplete blockage:**

Effective dose equivalent (mSv/MBq) with little uptake in the thyroid.

| | | | | | |
|---|---|---|---|---|---|
| Uptake: 0.5% | 3.0E-01 | 4.5E-01 | 6.9E-01 | 1.5E+00 | 2.8E+00 |
| Uptake: 1.0% | 5.2E-01 | 8.1E-01 | 1.2E+00 | 2.7E+00 | 5.3E+00 |
| Uptake: 2.0% | 9.7E-01 | 1.5E+00 | 2.4E+00 | 5.3E+00 | 1.0E+01 |

**Thyroid uptake 15%**

| **Organ** | **Absorbed dose per unit activity administered (mGy/MBq)** | | | | |
|---|---|---|---|---|---|
| | **Adult** | **15 years** | **10 years** | **5 years** | **1 year** |
| Adrenals | 3.6E-02 | 4.3E-02 | 7.1E-02 | 1.1E-01 | 2.2E-01 |
| Bladder wall | 5.2E-01 | 6.4E-01 | 9.8E-01 | 1.5E+00 | 2.9E+00 |
| Bone surfaces | 4.7E-02 | 6.7E-02 | 9.4E-02 | 1.4E-01 | 2.4E-01 |
| Breast | 4.3E-02 | 4.3E-02 | 8.1E-02 | 1.3E-01 | 2.5E-01 |
| GI tract | | | | | |
| Stomach wall | 4.6E-01 | 5.8E-01 | 8.4E-01 | 1.5E+00 | 2.9E+00 |
| Small intest | 2.8E-01 | 3.5E-01 | 6.2E-01 | 1.0E+00 | 2.0E+00 |
| ULI wall | 5.9E-02 | 6.5E-02 | 1.0E-01 | 1.6E-01 | 2.8E-01 |
| LLI wall | 4.2E-02 | 5.3E-02 | 8.2E-02 | 1.3E-01 | 2.3E-01 |
| Kidneys | 6.0E-02 | 7.5E-02 | 1.1E-01 | 1.7E-01 | 2.9E-01 |
| Liver | 3.2E-02 | 4.1E-02 | 6.8E-02 | 1.1E-01 | 2.2E-01 |
| Lungs | 5.3E-02 | 7.1E-02 | 1.2E-01 | 1.9E-01 | 3.3E-01 |
| Ovaries | 4.3E-02 | 5.9E-02 | 9.2E-02 | 1.4E-01 | 2.6E-01 |
| Pancreas | 5.2E-02 | 6.2E-02 | 1.0E-01 | 1.5E-01 | 2.7E-01 |
| Red marrow | 5.4E-02 | 7.4E-02 | 9.9E-02 | 1.4E-01 | 2.4E-01 |
| Spleen | 4.2E-02 | 5.1E-02 | 8.1E-02 | 1.2E-01 | 2.3E-01 |
| Testes | 2.8E-02 | 3.5E-02 | 5.8E-02 | 9.4E-02 | 1.8E-01 |
| Thyroid | 2.1E+02 | 3.4E+02 | 5.1E+02 | 1.1E+03 | 2.0E+03 |
| Uterus | 5.4E-02 | 6.8E-02 | 1.1E-01 | 1.7E-01 | 3.1E-01 |
| Other tissue | 6.5E-02 | 8.9E-02 | 1.4E-01 | 2.2E-01 | 4.0E-01 |
| **Effective dose equivalent (mSv/MBq)** | **6.6E+00** | **1.0E+01** | **1.5E+01** | **3.4E+01** | **6.2E+01** |

The effective dose equivalent (EDE) in an adult administered 5.55 GBq with 15% thyroid uptake is 36,630 mSv.

**Thyroid uptake 35%**

| **Organ** | **Absorbed dose per unit activity administered (mGy/MBq)** | | | | |
|---|---|---|---|---|---|
| | **Adult** | **15 years** | **10 years** | **5 years** | **1 year** |
| Adrenals | 4.2E-02 | 5.0E-02 | 8.7E-02 | 1.4E-01 | 2.8E-01 |
| Bladder wall | 4.0E-01 | 5.0E-01 | 7.6E-01 | 1.2E+00 | 2.3E+00 |
| Bone surfaces | 7.6E-02 | 1.2E-01 | 1.6E-01 | 2.3E-01 | 3.5E-01 |
| Breast | 6.7E-02 | 6.6E-02 | 1.3E-01 | 2.2E-01 | 4.0E-01 |
| GI tract | | | | | |
| Stomach wall | 4.6E-01 | 5.9E-01 | 8.5E-01 | 1.5E+00 | 3.0E+00 |
| Small intest | 2.8E-01 | 3.5E-01 | 6.2E-01 | 1.0E+00 | 2.0E+00 |
| ULI wall | 5.8E-02 | 6.5E-02 | 1.0E-01 | 1.7E-01 | 3.0E-01 |
| LLI wall | 4.0E-02 | 5.1E-02 | 8.0E-02 | 1.3E-01 | 2.4E-01 |
| Kidneys | 5.6E-02 | 7.2E-02 | 1.1E-01 | 1.7E-01 | 2.9E-01 |
| Liver | 3.7E-02 | 4.9E-02 | 8.2E-02 | 1.4E-01 | 2.7E-01 |
| Lungs | 9.0E-02 | 1.2E-01 | 2.1E-01 | 3.3E-01 | 5.6E-01 |
| Ovaries | 4.2E-02 | 5.7E-02 | 9.0E-02 | 1.4E-01 | 2.7E-01 |
| Pancreas | 5.4E-02 | 6.9E-02 | 1.1E-01 | 1.8E-01 | 3.2E-01 |
| Red marrow | 8.6E-02 | 1.2E-01 | 1.6E-01 | 2.2E-01 | 3.5E-01 |
| Spleen | 4.6E-02 | 5.9E-02 | 9.6E-02 | 1.5E-01 | 2.8E-01 |
| Testes | 2.6E-02 | 3.2E-02 | 5.4E-02 | 8.9E-02 | 1.8E-01 |
| Thyroid | 5.0E+02 | 7.9E+02 | 1.2E+03 | 2.6E+03 | 4.7E+03 |
| Uterus | 5.0E-02 | 6.3E-02 | 1.0E-01 | 1.6E-01 | 3.0E-01 |
| Other tissue | 1.1E-01 | 1.6E-01 | 2.6E-01 | 4.1E-01 | 7.1E-01 |
| **Effective dose equivalent (mSv/MBq)** | **1.5E+01** | **2.4E+01** | **3.6E+01** | **7.8E+01** | **1.4E+02** |

The effective dose equivalent (EDE) in an adult administered 5.55 GBq with 35% thyroid uptake is 83,250 mSv.

**Thyroid uptake 55%**

| Organ | Absorbed dose per unit activity administered (mGy/MBq) | | | | |
|---|---|---|---|---|---|
| | **Adult** | **15 years** | **10 years** | **5 years** | **1 year** |
| Adrenals | 4.9E-02 | 5.8E-02 | 1.1E-01 | 1.7E-01 | 3.4E-01 |
| Bladder wall | 2.9E-01 | 3.6E-01 | 5.4E-01 | 8.5E-01 | 1.6E+00 |
| Bone surfaces | 1.1E-01 | 1.7E-01 | 2.2E-01 | 3.2E-01 | 4.8E-01 |
| Breast | 9.1E-02 | 8.9E-02 | 1.9E-01 | 3.1E-01 | 5.6E-01 |
| GI tract | | | | | |
| Stomach wall | 4.6E-01 | 5.9E-01 | 8.6E-01 | 1.5E+00 | 3.0E+00 |
| Small intest | 2.8E-01 | 3.5E-01 | 6.2E-01 | 1.0E+00 | 3.0E+00 |
| ULI wall | 5.8E-02 | 6.7E-02 | 1.1E-01 | 1.8E-01 | 3.2E-01 |
| LLI wall | 3.9E-02 | 4.9E-02 | 7.8E-02 | 1.3E-01 | 2.4E-01 |
| Kidneys | 5.1 E-02 | 6.8E-02 | 1.0E-01 | 1.7E-01 | 2.9E-01 |
| Liver | 4.3E-02 | 5.8E-02 | 9.7E-02 | 1.7E-01 | 3.3E-01 |
| Lungs | 1.3E-01 | 1.8E-01 | 3.0E-01 | 4.8E-01 | 8.0E-01 |
| Ovaries | 4.1E-02 | 5.6E-02 | 9.0E-02 | 1.5E-01 | 2.7E-01 |
| Pancreas | 5.8E-02 | 7.6E-02 | 1.3E-01 | 2.1E-01 | 3.8E-01 |
| Red marrow | 1.2E-01 | 1.8E-01 | 2.2E-01 | 2.9E-01 | 4.6E-01 |
| Spleen | 5.1E-02 | 6.8E-02 | 1.1E-01 | 1.7E-01 | 3.3E-01 |
| Testes | 2.6E-02 | 3.1E-02 | 5.2E-02 | 8.7E-02 | 1.7E-01 |
| Thyroid | 7.9E+02 | 1.2E+03 | 1.9E+03 | 4.1E+03 | 7.4E+03 |
| Uterus | 4.6E-02 | 6.0E-02 | 9.9E-02 | 1.6E-01 | 3.0E-01 |
| Other tissue | 1.6E-01 | 2.4E-01 | 3.7E-01 | 5.9E-01 | 1.0E+00 |
| **Effective dose equivalent (mSv/MBq)** | **2.4E+01** | **3.7E+01** | **5.6E+01** | **1.2E+02** | **2.2E+02** |

For this product, the effective dose equivalent (EDE) to an adult with 55% thyroid uptake resulting from the administration of a 5.55GBq capsule is 133,200mSv.

## 8 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

This radiopharmaceutical may be received, used and administered only by authorised persons, in designated clinical setting. Their receipt, storage, use, transfer and disposal are subject to the regulations and/or appropriate licences of the local competent official organisation. (see section 6.6).

The administration of radiopharmaceuticals creates risks for other persons from external radiation or contamination from spills of urine, vomiting, etc. Radiation protection precautions in accordance with national regulations must therefore be taken.

## 9 MANUFACTURER

GE Healthcare Buchler GmbH & Co. KG
Gieselweg 1
D-38110 Braunschweig
Germany

## 10 REGISTRATION HOLDER

Eldan Electronic Instruments Co.Ltd., P.O.Box 7641, Petach Tiqva 4917001

## 11 LICENSE NUMBER

144-46-31928-00



The content of this leaflet was approved by the Ministry of Health in 02/2017 and updated according to the guidelines of the Ministry of Health in 06/2018.