IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0240/031/001
Case No: 2025875

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

GE Healthcare Limited

Amersham Place, **Little Chalfont**, **Buckinghamshire**, **HP7 9NA**, **United Kingdom**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Theracap, Sodium Iodide [131I] capsules for therapeutic use Ph. Eur

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **27/02/2008** until **12/04/2012**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Theracap, Sodium Iodide [^{131}I] capsules for therapeutic use Ph. Eur.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

THERACAP^{131} is presented as a single yellow capsule containing sodium iodide [^{131}I] in the following dosage range; 37-2035 MBq in 37MBq steps and 2.22 - 5.55GBq in 185MBq steps at the activity reference date. Each capsule contains a maximum of 20 µg of sodium iodide. The specific activity of the sodium iodide [^{131}I] is not less than 222GBq/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 8.04 days. It decays by emission of gamma radiations of 364 KeV (81.6%), 637 KeV (7.1%) and 284 KeV (6.2%) and beta radiations of maximal energy of 606 KeV to stable Xenon 131.

3 PHARMACEUTICAL FORM

Capsules

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 iodide [^{131}I] 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 - 800MBq 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 - 3700MBq. It depends on the remnant size and radioiodine uptake. In subsequent treatment for metastases, administered activity is in the range 3700 - 11100MBq.

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 equations:

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

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

Correction factors given for guidance are proposed below.

Fraction of adult dose		
3Kg = 0.1	22 Kg = 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, 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 iodide [^{131}I] 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

- 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 are 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 precautions for use

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.

Radiopharmaceuticals should be prepared by the user in a manner which satisfies both radiological and pharmaceutical quality requirements.

This preparation is likely to result in relatively a high radiation dose to most patients (see sections 4.8 and 5.4).

The administration of high dose radioiodine may result in significant environmental hazard. These may be of concern to the immediate family of those individuals undergoing treatment or the general public depending on the level of activity administered. Suitable precautions should be taken concerning the activity eliminated by the patients in order to avoid any contamination.

There is little evidence of an increased incidence of cancer, leukaemia or mutations in man with respect to patients treated for benign thyroid disease with radioiodine, despite extensive use. In the treatment of children and young people, however, account must be taken of the greater sensitivity of a childs tissue and the greater life expectancy of such patients. The risks must also be weighed up against those of other possible treatments. In the treatment of malignant thyroid disease, a higher incidence of bladder cancer has been reported in one study of patients receiving greater than 3,700MBq iodine-131. Another study has reported a small excess of leukaemia in patients receiving very high doses. A cumulative total activity higher than 26,000MBq is therefore not advisable.

The therapeutic administration of sodium iodide [^{131}I] capsules in patients with significant renal impairment, in which an activity adjustment is necessary, requires special attention.

To avoid sialadenitis which may complicate high dose radioiodine administration, the patient may be advised to take sweets or drinks containing citric acid which will stimulate saliva excretion.

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. A period of ten days is recommended for triiodothyonine and six weeks for thyroxine. They should be restarted two weeks after treatment. Similarly, carbimazole and propylthiouracil should be stopped five days prior to treatment of hyperthyroidism and restarted several days later.

4.5 Interaction with other medicinal products and other forms of interaction

Many pharmacological agents are known to interact with radioiodide. These may do so by a variety of mechanisms which can affect the protein binding, the pharmacokinetics or influence the dynamic effects of labelled iodide. It is therefore necessary to take a full drug history and ascertain whether any medications are required to be withheld prior to the administration of sodium iodide [^{131}I]. For example, dynamic, antithyroid agents, carbimazole (or other imidazole derivatives such as propylthiouracil), salicylates, steroids, sodium nitroprusside, sodium sulfobromophtalein, perchlorate, miscellaneous agents (anticoagulants, anti-histamines, antiparasitics, penicillins, sulphonamides, tolbutamide, thiopental), are normally withheld for 1 week; phenylbutazone for 1-2 weeks; expectorants, vitamins for 2 weeks; natural or synthetic thyroid preparations (levothyroxine sodium, sodium liothyronine, thyroid extract) for 2-3 weeks; amiodarone, benzodiazepines, lithium for 4 weeks; topical iodides for 1-9 months; and for intravenous contrast agents, oral cholecystographic agents, iodine containing contrast media for a period of up to 1 year.

4.6 Pregnancy and lactation

Sodium iodide [^{131}I] 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 11-511mGy, and the foetal thyroid gland avidly concentrates iodine during the second and third trimesters).

When it is necessary to administer a radioactive medicinal product 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 iodide [^{131}I] should be advised NOT to become pregnant within four months of administration.

Before administering a radioactive medicinal product to a mother who is breast feeding consideration should be given as to whether the investigation could be reasonably delayed until the mother has ceased breast feeding and as to whether the most appropriate choice of radiopharmaceutical has been made, bearing in mind the secretion of activity in breast milk. Breast feeding should be discontinued indefinitely after sodium iodide [^{131}I] administration.

4.7 Effects on ability to drive and use machines

No effects on the ability to drive or to operate machinery are to be expected after use of the drug.

4.8 Undesirable effects

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.

Some cases of adverse reactions have been reported following the administration of sodium iodide [^{131}I], including nausea, vomiting and unspecified possible allergic phenomena. Nausea and vomiting are more frequent after administration by the oral route especially after therapeutic doses and the risks of contamination following the occurrence of vomiting have to be considered.

- Early consequences

Therapeutic quantities of sodium iodide [^{131}I] may worsen existing hyperthyroidism temporarily. High levels of radioactivity may lead to gastrointestinal disturbance, usually within the first hours or days after administration. The incidence of gastrointestinal upset can be as high as 67%. This can easily be prevented or counteracted by means of symptomatic treatment.

With high dose radioiodine treatment, 1-3 days after administration, the patient may experience transient inflammatory thyroiditis and tracheitis, with a possibility of severe tracheal constriction, especially where there is existing tracheal stenosis. Sialadenitis may occur, with swelling and pain in the salivary glands, partial loss of taste and dry mouth. Incidence varies from 10% (with precautions) and 60% (without precautions). Sialadenitis is usually reversible spontaneously or with antiinflammatory treatment but cases have occasionally been described of dose-dependent persistent loss of taste and dry mouth, followed by loss of teeth. The radiation exposure of the salivary glands should be reduced by stimulating saliva excretion with acidic substances.

High levels of uptake of radioiodine given to the patients can be associated with local pain, discomfort and oedema in the tissue taking up the radionuclide.

In the treatment of metastasizing thyroid carcinomas with CNS involvement, the possibility of local cerebral oedema and/or an increasing existing cerebral oedema must also be borne in mind.

- Late consequences

Dose dependent hypothyroidism may occur as a late consequence of radioiodine treatment of hyperthyroidism. This may manifest itself weeks or years after treatment, requiring suitable timed measurement of thyroid function and appropriate thyroid replacement therapy. The incidence of hypothyroidism, generally not seen until 6-12 weeks, following radioiodine has been variously reported as between 2 - 70%.

Occasionally, cases of transient hypoparathyroidism have been observed after radioiodine, they must be monitored accordingly and treated with replacement therapy.

As a late consequence a single administration of over 5000MBq or an interval of below 6 months are more likely to be associated with reversible or in very rare cases irreversible bone marrow depression developing, with isolated thrombocytopenia or erythrocytopenia, which may be fatal. Transient leucocytosis is frequently observed.

Epidemiological studies report a higher incidence of stomach cancer in patients receiving sodium iodide [^{131}I].

After higher activities, typically those used in the treatment of thyroid malignancies, an increased incidence of leukaemia has been observed. There may also be a small increase in bladder and breast cancers.

Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary effects. The radiation dose resulting from therapeutic exposure may result in higher incidence of cancer and mutations. In all cases it is necessary to ensure that the risks of the radiation are less than from the disease itself. The radiation dose delivered (EDE) after therapeutic doses of sodium iodide [^{131}I] is higher than 20mSv.

4.9 Overdose

This agent is intended for use by competent personnel within a hospital setting. As such the risk of overdose is theoretical. The risks relate to the inadvertent administration of excess radioactivity. 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

ATC Code: V10X A01

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 0.5mm.

5.2 Pharmacokinetic properties

After oral administration sodium iodide [^{131}I] is absorbed rapidly from the upper gastrointestinal tract (90% in 60 minutes). The pharmacokinetics follow that of unlabelled iodide. After entering the bloodstream it is distributed in the extra thyroidal compartment. From here it is predominantly taken up by the thyroid or excreted renally.

Small amounts of sodium iodide [^{131}I] are taken up by salivary glands, gastric mucosa and would also be localised in breast milk, the placenta and choroid 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 iodide [^{131}I], 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

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 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.

IODIDE
Thyroid blocked, uptake 0%

^{131}I 8.04 days

	Absorbed dose per unit activity administered (mGy/MBq)				
Organ	**Adult**	**15 Year**	**10 Year**	**5 Year**	**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-02	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	5.4 E-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%	3.0 E-01	4.5 E-01	6.9 E-01	1.5 E+00	2.8 E+00
uptake 1.0%	5.2 E-01	8.1 E-01	1.2 E+00	2.7 E+00	5.3 E+00
uptake 2.0%	9.7 E-01	1.5 E+00	2.4 E+00	5.3 E+00	1.0 E+01

Thyroid uptake 15%

	Absorbed dose per unit activity administered (mGy/MBq)				
Organ	**Adult**	**15 Year**	**10 Year**	**5 Year**	**1 Year**
Adrenals	3.6E-02	4.3E-02	7.1E-02	1.1E-01	2.2 E-01

Bladder wall	5.2E-01	6.4E-01	9.8E-01	1.5E+00	2.9 E-00
Bone surfaces	4.7E-02	6.7E-02	9.4E-02	1.4E-01	2.4 E-01
Breast	4.3E-02	4.3E-02	8.1E-02	1.3E-01	2.5 E-01
GI tract Stomach wall Small intest ULI wall LLI wall	 4.6E-01 2.8E-01 5.9E-02 4.2E-02	 5.8E-01 3.5E-01 6.5E-02 5.3E-02	 8.4E-01 6.2E-01 1.0E-01 8.2E-02	 1.5E+00 1.0E+00 1.6E-01 1.3E-01	 2.9E-00 2.0E-00 2.8E-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%

	Absorbed dose per unit activity administered (mGy/MBq)				
Organ	**Adult**	**15 Year**	**10 Year**	**5 Year**	**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 Small intest ULI wall LLI wall	 4.6E-01 2.8E-01 5.8E-02 4.0E-02	 5.9E-01 3.5E-01 6.5E-02 5.1E-02	 8.5E-01 6.2E-01 1.0E-01 8.0E-02	 1.5E+00 1.0E+00 1.7E-01 1.3E-01	 3.0E+00 2.0E+00 3.0E-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%

	Absorbed dose per unit activity administered (mGy/MBq)				
Organ	**Adult**	**15 Year**	**10 Year**	**5 Year**	**1 Year**
Adrenals	4.9E-02	5.8E-02	1.1E-01	1.7 E-01	3.4E-01
Bladder wall	2.9E-01	3.6E-01	5.4E-01	8.5 E-01	1.6E-00
Bone surfaces	1.1E-01	1.7E-01	2.2E-01	3.2 E-01	4.8E-01
Breast	9.1E-02	8.9E-02	1.9E-01	3.1 E-01	5.6E-01
GI tract					
Stomach wall	4.6E-01	5.9E-01	8.6E-01	1.5 E-00	3.0E+00
Small intest	2.8E-01	3.5E-01	6.2E-01	1.0 E+00	2.0E+00
ULI wall	5.8E-02	6.7E-02	1.1E-01	1.8 E-01	3.2E-01
LLI wall	3.9E-02	4.9E-02	7.8E-02	1.3 E-01	2.4E-01
Kidneys	5.1E-02	6.8E-02	1.0E-01	1.7 E-01	2.9E-01
Liver	4.3E-02	5.8E-02	9.7E-02	1.7 E-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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium thiosulphate
Disodium hydrogen orthophosphate
Sodium hydroxide
Gelatin capsule:
Yellow iron oxide
Titanium dioxide
Gelatin

6.2 Incompatibilities

There are no known incompatibilities.

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

The product should be stored below 25^{o}C. Do not freeze..

Storage should be in accordance with national regulations for radioactive material.

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.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

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.

7 MARKETING AUTHORISATION HOLDER

GE Healthcare Limited
Amersham Place
Little Chalfont
Buckinghamshire
HP7 9NA
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 240/31/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation 13th April 2007.

10 DATE OF REVISION OF THE TEXT

November 2007