

Package leaflet: Information for the patient

Sodium Iodide (I131) Capsule T 37-7400 MBq, hard capsule

sodium iodide (^{131}I)

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your nuclear medicine doctor who will supervise the procedure.
- If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Sodium Iodide (I131) Capsule T is and what it is used for
2. What you need to know before Sodium Iodide (I131) Capsule T is used
3. How Sodium Iodide (I131) Capsule T is used
4. Possible side effects
5. How Sodium Iodide (I131) Capsule T is stored
6. Contents of the pack and other information

1. What Sodium Iodide (I131) Capsule T is and what it is used for

Sodium Iodide (I131) Capsule T is a medicine used in adults, children and adolescents to treat:

- thyroid gland tumours and
- overactive thyroid gland

This medicine contains sodium iodide (^{131}I), a radioactive substance which accumulates in certain organs such as, the thyroid gland.

This medicine is radioactive but your doctors consider that the medicine's beneficial effect on your condition outweigh the possible harm from the radiation.

2. What you need to know before Sodium Iodide (I131) Capsule T is used

Sodium Iodide (I131) Capsule T must not be used,

if you are

- allergic to sodium iodide or any of the other ingredients of this medicine (listed in section 6)
- pregnant
- breast-feeding

if you have

- swallowing problems
- obstructed gullet
- stomach problems like inflammation of the stomach (gastritis) and gastro-duodenal ulcer
- reduced stomach or bowel movement

If any of these apply to you, **tell your nuclear medicine doctor.**

Warnings and precautions

Tell the nuclear medicine doctor

- if you have reduced kidney function.
- if you have problems passing urine,
- if you have digestive or stomach problems,
- if protruding eyes are part of the symptoms of the disease you are suffering from (Graves' disease-induced ophthalmopathy).

If any of these apply to you, talk to your nuclear medicine doctor. Sodium Iodide (I131) Capsule T may not be suitable for you.

Your doctor will inform you if you need to take any special precautions after using this medicine. Speak with your nuclear medicine doctor if you have any questions.

Low sodium blood levels have been observed in elderly patients who have had their thyroid removed. This event is most likely to occur in women and in patients taking medicines that increase the amount of water and sodium that is excreted in the urine (diuretics, such as hydrochlorothiazide). If you are included in some of these groups, your doctor may perform regular blood tests to check the amount of electrolytes (e.g. sodium) in your blood.

Before you take Sodium Iodide (I131) Capsule T you should

- Follow a low iodine diet.
- drink plenty of water before the start of the procedure so that you pass urine as often as possible in the first hours after taking Sodium Iodide (I131) Capsule T.
- be fasting on the day of application.

Children and adolescents

Talk to your nuclear medicine doctor if you are under 18 years old, or if you cannot swallow a capsule.

Other medicines and Sodium Iodide (I131) Capsule T

Tell your nuclear medicine doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Please tell your nuclear medicine doctor if you are taking, or have been given, any of the following medicines or substances, since they may affect how well this treatment works.

Your doctor may recommend that you stop the following medicines before treatment:

- **medicines to reduce thyroid gland function** such as carbimazole, methimazole, propylthiouracil, perchlorate for 1 week;
- **salicylates:** medicines to reduce pain, fever or inflammation such as aspirin for 1 week;
- **cortisone:** medicines to reduce inflammation or prevent organ transplant rejection for 1 week;
- **sodium nitroprusside:** a medicine to reduce high blood pressure, and also used during an operation for 1 week;
- **sodium sulfobromophthalein:** a medicine to test liver function for 1 week;
- other medicines for 1 week
 - to **reduce blood coagulation**
 - to **treat parasitic** infestation
 - **antihistamines:** used to treat allergies
 - **penicillins** and **sulphonamides:** antibiotics
 - **tolbutamide:** a medicine to reduce blood sugar
- **thiopental:** an anaesthetic used in operations to reduce brain pressure, and also to treat serious epileptic fits for 1 week;

- **phenylbutazone:** a medicine to reduce pain and inflammation for 1-2 weeks;
- iodine containing **medicines to help free the airways of sputum** for 2 weeks;
- **iodide** containing medicines which are used only on a restricted area of the body for 1-9 months;
- iodine containing **contrast agents** up to 1 year
- **vitamins** containing iodine salts for 2 weeks;
- medicines containing **thyroid hormones** such as, levothyroxine (for 4 weeks) or triiodothyronine (for 2 weeks);
- **benzodiazepines:** medicines which calm mood and help patients sleep and relax muscles for 4 weeks;
- **lithium:** a medicine to treat bipolar for 4 weeks;
- **amiodarone:** a medicine to treat heart rhythm disorders for 3-6 months;

Sodium Iodide (I131) Capsule T with food

Your doctor may recommend a low iodine diet before treatment and may ask you to avoid foods such as shellfish and crustaceans.

Pregnancy and breast-feeding

This medicine must not be used during pregnancy. Therefore, **you must tell the nuclear medicine doctor before taking Sodium Iodide (I131) Capsule T** if there is a possibility you might be pregnant or if you have missed your period, or think you may be pregnant or are planning to have a baby.

If you are pregnant

Do not take Sodium Iodide (I131) Capsule T if you are pregnant. Any possibility of pregnancy must be ruled out before using this medicine.

Contraception in males and females

Women should not become pregnant for at least 6 months after using Sodium Iodide (I131) Capsule T. Women are advised to use contraception for a time period of 6 months. As a precaution, men should not father a child for a time period of 6 months after treatment with Sodium Iodide (I131) Capsule T to allow the replacement of irradiated by non-irradiated spermatozoa.

Fertility

Treatment with Sodium Iodide (I131) Capsule T may temporarily reduce fertility in men and women.

In men, high doses of sodium iodide (¹³¹I) may affect **sperm production** temporarily. If you would ever like to father a child, speak to your doctor about saving your sperm in a sperm bank.

If you are breast-feeding

Tell your doctor if you are breast-feeding because you should **stop breast-feeding 8 weeks before treatment. Breast-feeding should not be resumed after treatment with Sodium Iodide (I131) Capsule T.**

Driving and using machines

It is considered unlikely that Sodium Iodide (I131) Capsule T affect your ability to drive or to use machines.

Sodium Iodide (I131) Capsule T contains sodium and sugar

This medicine contains 63.5 mg of sodium (main component of cooking/table salt) per capsule. This is equivalent to 3 % of the recommended maximum daily dietary intake of sodium for an adult. This is to be taken into consideration if you are on a controlled sodium diet.

This medicine contains sucrose, a type of sugar. If you have been told by your doctor that you have an intolerance to sucrose, contact your doctor before taking this medicine.

3. How Sodium Iodide (I131) Capsule T is used

There are strict laws on the use, handling and disposal of radioactive products for medical treatment. Sodium Iodide (I131) Capsule T will only be used in special, controlled areas. This medicine will only be given to you by people who are trained and qualified to use it safely. These people will take special care to use this medicine safely and they will talk to you about what they are doing.

The nuclear medicine doctor supervising the procedure will decide on the right dose of Sodium Iodide (I131) Capsule T for you. It will be the smallest quantity necessary to get the desired effect.

Sodium Iodide (I131) Capsule T is given as one single capsule by specialists, who will take responsibility for any necessary precautions.

The doses usually recommended for an adult are:

- 200-800 MBq to treat overactive thyroid gland
- 1,850-3,700 MBq for partial or complete removal of the thyroid gland and for treating the spread of cancer cells, known as metastases,
- 3,700-11,100 MBq for follow up treatment of metastases.

MBq (megabecquerel) is the unit used to measure the amount radioactivity of the medicine.

Use in children and adolescents aged under 18 years

Lower doses are used for children and adolescents.

How Sodium Iodide (I131) Capsule T is given and what the procedure involves

Sodium Iodide (I131) Capsule T is given to you as one single capsule.

Your stomach should be empty when you take the capsule.

Take the capsule with plenty of water so that it enters your stomach as quickly as possible.

Young children should take the capsule together with mashed food.

Drink as much water as possible after you take the capsule and the day after treatment. This will wash away the active substance from your bladder.

Duration of the procedure

Your nuclear medicine doctor will tell you how long the procedure will take.

After you take Sodium Iodide (I131) Capsule T

The nuclear medicine doctor will tell you if you need to take any special precautions after receiving this medicine. Particularly, you

- must avoid any close contact with infants and pregnant women for a few days. Your nuclear medicine doctor will tell you how long this should be.
- should drink plenty of fluids and pass urine frequently in order to remove the medicine from your body
- should flush the toilet carefully and wash your hands thoroughly as your bodily fluids will be radioactive for a few days
- should have drinks or sweets that contain citric acid, e.g. orange, lemon or lime juice to help produce saliva and stop the saliva building up in your saliva glands
- should have laxatives to stimulate the bowel, if you have less than one bowel movement per day.

Your blood, stools, urine or possible vomit may be radioactive for a few days and should not come into contact with other people.

Contact your nuclear medicine doctor if you have any questions.

If you have been given more Sodium Iodide (I131) Capsule T than you should

An overdose is unlikely because you will only receive a single dose of Sodium Iodide (I131) Capsule T precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the case of an overdose, you will receive the appropriate treatment. Should you have any further question on the use of Sodium Iodide (I131) Capsule T, please ask the nuclear medicine doctor who supervises the procedure.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Frequent adverse reactions are: hypothyroidism (an underactive thyroid gland), temporary hyperthyroidism (an overactive thyroid gland), salivary and tear gland disorders, and local radiation effects. In cancer treatment, additionally stomach and gut side effects and reduction in the production of blood cells in the bone marrow may frequently occur.

If you have a serious allergic reaction, which causes difficulty in breathing or dizziness, or if you have severe overactive thyroid crisis, contact your doctor immediately.

All the side effects with Sodium Iodide (I131) Capsule T are listed below, grouped according to the condition Sodium Iodide (I131) Capsule T is being used for as they depend on the doses used for the different treatments.

Treatment of overactive thyroid gland

Very common (may affect more than 1 in 10 people):

- underactive thyroid
- a type of eye inflammation, called endocrine ophthalmopathy (after treatment of Graves' disease)

Common (may affect up to 1 in 10 people):

- temporarily overactive thyroid
- salivary gland inflammation

Very rare (may affect up to 1 in 10,000 people):

- vocal cord paralysis

Frequency not known (frequency cannot be estimated from the available data)

- serious allergic reaction which causes difficulty in breathing or dizziness
- severe overactive thyroid crisis
- thyroid inflammation
- reduced tear gland function characterised with dry eyes
- reduction or loss of parathyroid hormone production with tingling in the hands, fingers, and around the mouth to more severe forms of muscle cramps
- thyroid hormone deficiency in the offspring
- abnormal function of the liver
- iodo acne (acne like rash)
- local swelling

Treatment of cancers

Very common (may affect more than 1 in 10 people):

- bone marrow disorder with severe reduction in blood cells which can cause weakness, bruising or make infections more likely

- lack of red blood cells
- bone marrow failure with reduction of red blood cells, white blood cells, or both
- disturbance or loss of the sense of smell or taste
- nausea (feeling sick)
- decreased appetite
- loss of function of the ovaries
- disturbed menstrual cycle
- flu-like illness
- headache, neck pain
- extreme tiredness or drowsiness
- inflammation causing red, watery and itchy eyes
- salivary gland inflammation with symptoms such as dry mouth, nose and eyes; tooth decay, tooth loss

Common (may affect up to 1 in 10 people):

- lack of white blood cells or platelets
- runny nose
- breathing difficulty
- vomiting
- areas of tissue swelling

Uncommon (may affect up to 1 in 100 people):

- abnormal, cancerous increase of white blood cells

Rare (may affect up to 1 in 1000 people):

- severe or temporarily overactive thyroid

Frequency not known (frequency cannot be estimated from the available data):

- serious allergic reaction which causes difficulty in breathing or dizziness
- cancer, such as on the bladder, large bowel, stomach, breast
- permanent or severe reduction of blood cell production in the bone marrow
- thyroid inflammation
- reduction or loss of parathyroid hormone production
- increased parathyroid hormone production
- underactive thyroid
- inflammation of the trachea and/or throat narrowing or both
- proliferation of connective tissue in the lungs
- difficulty or wheezy breathing
- lung inflammation
- vocal cord paralysis, hoarseness, reduced ability to produce voice sounds
- mouth and throat pain
- fluid build-up in the brain
- inflammation of the stomach lining
- difficulty in swallowing
- inflammation of the bladder
- decreased male fertility, low or loss of sperm
- thyroid hormone deficiency in the offspring
- abnormal function of the liver

Reporting of side effects

If you get any side effects, talk to your Nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance; Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sodium Iodide (I131) Capsule T

You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in appropriate premises. It will be stored in accordance with national regulation on radioactive materials.

The following information is intended for the specialist only.

Sodium Iodide (I131) Capsule T must not be used after the expiry date which is stated on the label after 'EXP'.

6. Contents of the pack and other information

What Sodium Iodide (I131) Capsule T contains:

The active substance is iodide (I131) as sodium iodide

Each hard capsule contains 37 to 7400 MBq of sodium iodide (¹³¹I).

The other ingredients are:

gelatine (capsule shell), disodium phosphate dihydrate, sodium thiosulphate, sodium hydrogen carbonate, sodium hydroxide, sucrose, sodium chloride, water for injections

What Sodium Iodide (I131) Capsule T looks like and contents of the pack

Sodium Iodide (I131) Capsule T is a transparent capsule filled with white to light brown powder and is available in packages containing one capsule.

Marketing Authorisation Holder and Manufacturer

Curium Netherlands B.V.

Westerduinweg 3

1755 LE Petten

The Netherlands

This leaflet was last revised in 11/2021

The following information is intended for medical or healthcare professionals only: The complete Summary of Product Characteristics (SmPC) of Sodium Iodide (I131) Capsule T is provided as a separate document in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical. Please refer to the SmPC of Sodium Iodide (I131) Capsule T.