Package leaflet: Information for the patient

Sodium iodide $Na^{131}I$ POLATOM, capsules for therapeutic use
37-5500 MBq, hard capsules
Natrii iodidi (^{131}I) capsulae ad usum therapeuticum

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.

What is in this leaflet:

1. What Sodium iodide $Na^{131}I$ POLATOM, capsules for therapeutic use is and what it is used for

This medicine is a radiopharmaceutical product for therapy only.
The capsules containing different amount (activity) of radioactive sodium iodide (^{131}I) are administrated orally for thyroid diseases treatment.

Sodium iodide (^{131}I) is used for benign thyroid diseases treatment as listed below:
- treatment of thyroid nodular goitre
- treatment of Graves-Basedow's disease
- treatment of toxic multinodular goitre or autonomic nodule

It is also used in differentiated thyroid carcinoma treatment in the following indications:
- destruction of remaining tissues after surgery treatment (thyroid ablation)
- treatment of iodine-accumulating thyroid carcinoma metastases

The use of Sodium iodide $Na^{131}I$ POLATOM, capsules for therapeutic use does involve exposure to ionising radiation. Your doctor and the nuclear medicine doctor have considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical outweighs the risk due to radiation.

2. What you need to know before Sodium iodide $Na^{131}I$ POLATOM, capsules for therapeutic use is used

Sodium iodide $Na^{131}I$ POLATOM, capsules for therapeutic use must not be used:

- if you are pregnant or believe you may be pregnant or when pregnancy has not been excluded

- if you are breastfeeding
- if you are allergic to the active substance or any of the other ingredients of this medicine.

Warnings and precautions
Take special care with Sodium iodide $Na^{131}I$ POLATOM, capsules for therapeutic use:
- if your hyperthyroidism is uncontrolled
- if you have swallowing disorders and/or diseases of the gastrointestinal track causing food return or vomiting (due to the risk of misuse and radioactive contamination, the administration of iodine-131 in other than capsules pharmaceutical form or other than oral route, should be considered).

Due to the risk of radioactive contamination the special care should be taken if iodine -131 is administered to patients:
- with urinary incontinence
- who may not comply with the medical staff recommendations.

Patients exposed to high therapeutic doses of ^{131}I need to be hospitalized because of high radiological risk. The necessity of hospitalization is regulated by specified national law.
The administration of radiopharmaceuticals creates risks for other people from external radiation or contamination from spill of urine, vomiting, etc. Therefore basic hygiene rules should be observed.
To minimize radiation dose to the urinary bladder, it is recommended that you should drink plenty of fluids (about 1-1.5 L/day more than usually) after capsule administration, in order to help frequent voiding.

Before administration of Sodium iodide $Na^{131}I$ POLATOM, capsules for therapeutic use you should:
- stay on low iodine diet, especially limit consumption of sea originated products
- avoid any medicines containing the iodine (iodine containing vitamins, disinfectants, anti-cataract eye drugs, expectorants, amiodarone, contrast media use in some radiological studies)
- temporarily discontinue thyroid replacement therapy prior to radioiodine administration for thyroid carcinoma
- discontinue the treatment with antithyroid drugs (e.g. containing thiamazole or propyluracil) prior to hyperthyroidism treatment.

Other medicines and Sodium iodide $Na^{131}I$ POLATOM, capsules for therapeutic use
Tell your nuclear medicine doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.
Many pharmacological agents are known to interact with iodide. 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).

Sodium iodide $Na^{131}I$ POLATOM, capsules for therapeutic use with food and drink
A low iodine diet in patients prior to therapy will enhance (^{131}I) uptake into functioning thyroid tissue. It is recommended to be fasted for approximately 2 hours before and after swallowing the capsule, for better thyroid uptake.

Pregnancy and breast-feeding
Sodium iodide $Na^{131}I$ POLATOM, capsules for therapeutic use must not be used in pregnant or breast-feeding women.
You must inform the nuclear medicine doctor before the product administration if:
- there is a possibility you might be pregnant,
- you have missed your period,
- you are breast-feeding.

When in doubt, it is important to consult your nuclear medicine doctor who will supervise the procedure.
If you are pregnant it is important to inform your doctor.

Contraception for at least 4 months is recommended for both sexes after sodium iodide (^{131}I) therapy.

Breast-feeding should be discontinued after sodium iodide (^{131}I) administration.

Driving and using machines
No data.

Sodium iodide Na^{131}I POLATOM, capsules for therapeutic use contains sodium
The product contains from 80 to 96 mg of sodium in each capsule. This should be taken into account in patients on a low sodium diet.

3. How Sodium iodide Na^{131}I POLATOM, capsules for therapeutic use is used

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Sodium iodide Na^{131}I POLATOM, capsules for therapeutic use will only be used in special controlled areas. This product will only be handled and given to you by people who are trained and qualified to use it safely. These persons will take special care for the safe use of this product and will keep you informed of their actions.

Sodium iodide Na^{131}I POLATOM, capsules for therapeutic use is a product for oral administration with different amount (activity) of radioactive sodium iodide (^{131}I). The nuclear medicine doctor supervising the procedure will decide on the quantity of product (activity) to be used in your case. It will be the smallest quantity necessary to get the desired therapeutic effect.

Depending on the kind of thyroid disease the following therapeutic doses are recommended:
- treatment of hyperthyroidism and nodular goitre: 200-800MBq
- ablation of local thyroid residues following the operation of thyroid cancer: 1850-3700 MBq
- treatment of thyroid cancer metastases 3700-11100 MBq

(MBq- megabecquerel –the unit used to express radioactivity)

Use in children
The administration of Sodium iodide Na^{131}I POLATOM, capsules for therapeutic use in children has to be considered carefully by nuclear medicine doctor, based upon clinical needs and assessing of the risk/benefit ratio in this patient group. The dose is calculated similarly as in adults, however its reduction may be taken into consideration due to the child's age and weight.

After administration of Sodium iodide Na^{131}I POLATOM, capsules for therapeutic use, you should
- urinate frequently in order to eliminate the product from your body
- use contraception for both sexes for at least 4 months after treatment.

The administration of radiopharmaceuticals creates risks for other people from external radiation or contamination from spill of urine, vomiting, etc. Therefore after sodium iodide (^{131}I) administration you should:
- avoid close contact with other people, particularly with children and pregnant women for the period indicated by the doctor
- remove carefully the urine, stool and sweat residue, for the period indicated by the doctor

If you have been given more Sodium iodide $Na^{131}I$ POLATOM, capsules for therapeutic use than you should
An overdose is unlikely, because you will only receive a dose precisely controlled by the nuclear medicine doctor supervising the procedure. This product is supplied as a capsule of known radioactivity, what facilitates control of the dose administered to the patient.
However, in the case of an overdose, your doctor may recommend the use of thyroid blocking agents, or emetics and ask you to drink more fluids than usually in order to remove the traces of radiopharmaceutical from your body.

Should you have any further question on the use of the medicine, please ask the nuclear medicine doctor who supervises the procedure.

4. Possible side effects

Like all medicines Sodium iodide $Na^{131}I$ POLATOM, capsules for therapeutic use can cause side effects, although not everybody gets them.

Early consequences
Very common (observed in more than 1 patient in 10) early undesirable effects occurring in the first hours or days after drug administration, especially in patients treated by high radiation doses, include: radiation thyroiditis (manifesting by discomfort on the neck, rarely by severe pain of the neck, neck oedema), radiation sialadenitis (manifesting by their oedema, discomfort, rarely by severe pain of the neck), dry mouth, nausea, vomiting, tracheal obstruction.

In patients treated for thyroid cancer metastases to the lungs (usually repeatedly, with high radiation doses) toxic radiation pneumonia and/or lung fibrosis may occur. In the treatment of thyroid cancer metastases with cerebral nervous system involvement, the possibility of local cerebral oedema and/or an increasing of existing cerebral oedema must also be borne in mind.

Late consequences
Very common (observed in more than 1 patient in 10) late undesirable effect occurring in patients treated for benign thyroid diseases is hypothyroidism requiring thyroid hormone replacement therapy.

All below described undesirable effects occur with not known frequencies (cannot be estimated from the available data).
Increasing of blood thyroid hormones may occur in some patients few days (usually 7-10 days) after radioiodine administration. In patients without suitable thyroid function control it may cause occurrence of hyperthyroidism symptoms (similar to those on the beginning of the disease), or life-threatening thyroid crisis in extreme cases. In a small percentage of the patients threated from nodular goitre, Graves-Basedow disease may be induced.

As a late consequence, reversible or in very rare cases irreversible (mostly in patients treated with high doses) bone marrow failure may occur, including thrombocytopenia and/or leukopenia, less frequently erythrocytopenia.

Rarely in some patients with Graves-Basedow disease, especially smokers, exacerbation or occurrence of eyes protruding (thyroid ophtalmopathy) may be the consequence of radioiodine treatment. Equally rare, after radioiodine therapy for multinodular goitre, immune thyroiditis may occur. It is usually transient but may manifest itself as requiring treatment hyperthyroidism. Radioiodine thyroid cancer treatment may cause transient (exceptionally persistent) impairment of fertility in men and women.

Persistent malfunction of the salivary glands, including dry mouth, taste and smell disturbances (more often after repeated sodium I-131 administrations), less persistent malfunction of the salivary and/or

lacrimal glands with tears secretion (sicca syndrome) or tears drainage impairment (due to nasolacrimal ducts obstruction) may appear as the result of sodium iodide (^{131}I) administration.

Parathyroid disturbances – hypoparathyroidism or hyperparathyroidism occurred in the small group of patients after radioiodine therapy.

The exposure to ionising radiation may lead to cancer induction (in the case of high activities administration) and a potential for development of hereditary defects. The epidemiological data indicate enhanced occurrence of gastric cancer, bladder cancer, breast cancer and leukaemia in patients treated with sodium iodide (^{131}I).

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.

5. How Sodium iodide Na^{131}I POLATOM, capsules for therapeutic use is stored

You will not have to store this medicine.
Radiopharmaceuticals are stored under the responsibility of the specialist in appropriate premises. Storage of radiopharmaceuticals will be in accordance with national regulation on radioactive materials.

The following information is intended for the specialist only.
The product must not be used after the expiry date which is stated on the label.

6. Contents of the pack and other information

What Sodium iodide Na^{131}I POLATOM, capsules for therapeutic use contains:

- the active substance is sodium iodide (^{131}I) in activities from 37 MBq to 5500MBq
- the other ingredients are
  - Sodium carbonate
  - Sodium hydrogen carbonate
  - Disodium hydrophosphate dihydrate
  - Sodium thiosulfate pentahydrate
  - Hard gelatine capsule

What Sodium iodide Na^{131}I POLATOM, capsules for therapeutic use looks like and contents of the pack
The product is distributed as a single capsule in the vial.
The polypropylene vial is closed with a polypropylene stopper containing iodine absorber and placed in a shielding lead container. The package contains a single capsule. Each box is accompanied by a separate polypropylene applicator for capsule administration and radioactive source certificate.

Marketing Authorisation Holder

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For any more detailed information about this medicine, please contact your physician or the local representative of the Marketing Authorisation Holder.

This leaflet was last revised in:

The following information is intended for medical or healthcare professionals only:
Instructions for opening the container with the radioactive product using the applicator:

1. Check the radioactivity and calibration date placed on the outer package
2. Tear off the upper cover of the shipping container (metal tin).
3. Remove the upper styrofoam inlay.
4. Take the capsule shielding container out.
5. Tear the paper-foil mouthpiece wrapping and take out the mouthpiece
6. Open the shielding container containing the capsule. To do this, hold the bottom part of the container and pull the upper part upwards. The vial containing the capsule should remain in the shielding container.
7. Connect the mouthpiece to the vial. To do this, screw in the mouthpiece into the vial containing the capsule.
8. During the administration of the capsule it is recommended to keep the vial containing the capsule in the shielding container. The patient holding the shielding container in his hand takes the mouthpiece in his mouth and then tilts it to get the capsule from the vial through the mouthpiece. When required, it is possible to administer a capsule without using the shielding container. The patient grasps the mouthpiece, takes the capsule vial out from the shielding container, takes the mouthpiece in his mouth and then tilts it to get the capsule from the vial through the mouthpiece.
9. After the administration of the capsule, the mouthpiece and the vial should be disposed of. The shielding container should be returned to the manufacturer.
10. To disconnect the mouthpiece from the vial, put the vial with the mouthpiece in the shielding container, and then holding the container with your hand screw off the mouthpiece in order to disconnect it.
11. In order to measure the capsule activity, take the mouthpiece fixed to the capsule vial with the gripping device of the dose calibrator and load in the dose calibrator. When the measurement is finished remove the mouthpiece fixed to the capsule vial and place it back in the shielding container. When transferring the capsule to another room is necessary, the mouthpiece should be disconnected from the vial according to above instruction. After disconnecting the mouthpiece, cover the shielding container with a lid.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.