CONSUMER MEDICINE INFORMATION (CMI)

SODIUM IODIDE [131-I] THERAPY SOLUTION, ORAL LIQUID

1 Medicine name

Sodium Iodide [131]

2 Special advisory

Radiopharmaceuticals should be used only by physicians who are qualified by specific training in the safe use and handling of radionuclides produced by a nuclear reactor or particle accelerator, and whose experience and training have been approved by the appropriate government agency authorised to license the use of radionuclides.

Care should be taken to minimise radiation exposure to patients, consistent with proper patient management. As with other radioactive drugs, Sodium Iodide [¹³¹I] must be handled with care and appropriate safety measures should be used to minimise radiation exposure to clinical personnel.

3 Why am I using Sodium Iodide [¹³¹I] Therapy Solution?

You are being given the Sodium Iodide [¹³¹I] Therapy Solution, oral liquid for the treatment of treatment of hyperthyroidism, and the detection, treatment and ablation of residual functioning thyroid tissue in differentiated thyroid carcinoma.

Sodium Iodine (¹³¹I) is a radioisotope which emits high energy electrons (beta particles). When administered orally the Iodine-131 is rapidly absorbed from the gastrointestinal tract into the bloodstream and distributed in the extracellular fluid. A proportion is concentrated by thyroid tissue, where beta radiation from the Iodine-131 help reduce the activity of the tissue in proportion to the amount of Iodine-131 absorbed.

If you have any concerns about being given this solution, discuss them with your nuclear medicine specialist.

4 What should I know before I use Sodium Iodide [¹³¹I] Therapy Solution?

All medicines and diagnostic agents have risks and benefits associated with their usage. Your nuclear medicine physician or specialist has weighed the small risk of your being treated with a Sodium Iodide (¹³¹I) therapy Solution against the benefits it is expected you will receive from it.

Before you are given Sodium Iodide [¹³¹I] Therapy Solution, it is important to tell your nuclear medicine specialist or technologist if:

(i) You are pregnant or intend to become pregnant:

It is known that the Sodium Iodide (¹³¹I) may be harmful to an unborn baby when administered to a pregnant woman.

Sodium Iodide (131 I) will only be given in pregnancy after weighing the needs of the mother against any risk to the foetus.

If you intend to become pregnant consult your doctor about the advised waiting period.

(ii) You are breast-feeding:

It is normal practice to stop breastfeeding and substitute formula feeding from the time you are given the sodium iodide (¹³¹I). It is known that Sodium Iodide (¹³¹I) passes into breast milk.

(iii) You have eaten seafood, or foods with high iodine content lately:

Discuss your diet over the previous three days as iodine consumed in food may influence your treatment.

5 What if I am taking other medicines?

It is very important that you tell your doctors if you are taking any other medicines, including those you buy over the counter without a prescription from your pharmacy, supermarket, or health food store.

The constituents of medications you are taking could affect the results of this treatment. Your nuclear medicine specialist or technologist will advise you of what to do.

6 How do I use Sodium Iodide [¹³¹I] Therapy Solution?

How it is given:

Sodium Iodide (¹³¹I) therapy Solution is for oral administration only and be administered by qualified staff with specific training in the safe use and handling of radiopharmaceuticals.

Test procedure:

After taking your Sodium Iodide (¹³¹I) Solution you may be asked to stay in hospital for a period (spanning from few hours to few days) to monitor the treatment.

After your treatment you may be asked to have another scan, similar to your original diagnostic scan, at a later date.

7 What should I know while using - Sodium Iodide [¹³¹I] Therapy Solution, oral liquid.

Preparation:

Usually, no preparation is required for these tests. Specific instructions are given when any preparation is required.

After you are given the Sodium Iodide [¹³¹I] Therapy Solution:

- Directly after ingesting this product, you have radioactive material in you. You will be shielded from your surroundings for some time. Your stools, urine or vomit are considered radioactive and should be disposed of with care so they will not come into contact with others.
- Urinate frequently in order to eliminate the product from your body.
- Speak to your doctor if you are intending to father a child or intending to fall pregnant, you may have to wait for some period prior to this.

Your discharge from hospital and after you go home:

Continue your day-to-day activities. However, it is IMPORTANT to observe the following for one week after the treatment as the Iodine-131 continues to leave your body:

- Avoid close physical contact with children and pregnant women.
- Avoid being closer than 1 metre to other persons for an extended duration.
- Drink plenty of fluids.
- Observe good personal hygiene in order to prevent the spread of radioactive contamination.
- Shower daily and frequently wash off excess perspiration.

Your doctor will tell you if you need to take any special precautions after receiving Sodium Iodide (¹³¹I) Solution, oral liquid.

8 Are there any side effects?

Like all medicines, this medicine can cause side effects, although not everybody gets them. Tell your nuclear medicine specialist or technologist as soon as possible if you do not feel well after taking your Sodium Iodine (¹³¹I) therapy Solution.

Rare minor reactions such as nausea, vomiting, increased heartbeat, itching and rash have been reported with the use of Sodium Iodide (¹³¹I) therapy Solution.

When larger doses of lodine-131 are used, reported sided effects include radiation thyroiditis, sialitis and transient worsening of hyperthyroidism.

Potential effects of a high dose of Iodine-131 include nausea, pulmonary fibrosis, bone marrow depression, leukaemia, and acute thyroid crisis.

9 Sponsor

ANSTO New Illawarra Rd, Lucas Heights NSW 2234, Australia

Mailing address: ANSTO, Locked Bag 2001 Kirrawee DC NSW 2232, Australia

Telephone: 1800 251 572

E-mail: health@ansto.gov.au Website: <u>www.ansto.gov.au</u>

Product Code: 10019: 50MBq – 1200MBq 10234: 1201MBq – 16,000MBq

Australian Registration Number: AUST R: 22807 (200 MBq/mL) AUST R: 48267 (2000 MBq/mL)

10 Date of revision

18 January 2022

