

PROFESSIONAL INFORMATION

S4

1 NAME OF THE MEDICINE

¹²³I-CAPSULES, 5 to 370 MBq (\pm 10%) per capsule.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

¹²³I-Capsules contain iodine-123, obtainable from 5 to 370 MBq (\pm 10 %) per capsule.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

¹²³I-Capsules are clear capsules containing radioactive material and are packed in a glass container inside a lead pot. The ¹²³I-Capsules are only manufactured on order. The delivered amount of iodine-123 per capsule will be in compliance with the order within the limits of 5 to 370 MBq (\pm 10 %). The amount of iodine-123 is indicated on the label affixed to the lead pot.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Iodine-123 is suitable for diagnostic examinations of the thyroid and the diagnosis of thyroid cancer.

4.2 Posology and method of administration

One capsule to be administered orally before a diagnostic examination is conducted after a suitable lapse of time. The amount of iodine-123 in the capsule varies from 5 to 370 MBq according to the amount ordered for a specific diagnostic examination.

4.3 Contraindications

Sensitivity to iodine.

4.4 Special warnings and precautions for use

¹²³I-Capsules are radioactive and should only be handled and administered by legally authorised personnel.

The ¹²³I-Capsules are not recommended for pregnant patients. Since iodine-123 is excreted in human milk, formula feeding should be substituted for breastfeeding if ¹²³I-Capsules must be administered to the mother during lactation.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

The safety of this preparation in pregnancy has not been established. Since iodine-123 is excreted in human milk, formula feeding should be substituted for breastfeeding if ¹²³I-Capsules must be administered to the mother during lactation (see section **4.4. Special warnings and precautions for use**).

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been

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performed.

4.8 Undesirable effects

No side-effects are known.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form" found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

4.9 Overdose

No symptoms of overdosage are known.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A. 35 Radiopharmaceuticals.

Iodine is absorbed through active transport by the cells of the thyroid gland. The absorption is activated by thyreotropin. Consequently, the radioactive iodine will also be concentrated into the thyroid gland.

5.2 Pharmacokinetic properties

No absorption studies were performed with this product.

5.3 Preclinical safety data

No additional preclinical information, relevant to the indication, is presented.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Anhydrous glucose (Dextrose),
Gelatine capsule (size 1, clear and colourless) and
Sodium hydroxide solution (0,01 N).

6.2 Incompatibilities

None known.

6.3 Shelf life

The product remains stable until 5 hours after calibration (reference) time.

6.4 Special precautions for storage

The glass container with the ¹²³I-Capsule must be stored inside the lead pot in which it is packed. The capsule may be kept at room temperature (at or below 30 °C) until administered to a patient.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

One clear ¹²³I-Capsule is packed in a glass container inside a lead pot. The label is affixed to the lead pot.

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6.6 Special precautions for disposal

The contents of the vial are radioactive. Radiopharmaceuticals should only be disposed by appropriately qualified persons.

7 HOLDER OF CERTIFICATE OF REGISTRATION

iThemba LABS
Old Faure Road
FAURE
Cape Town, 7131

8 REGISTRATION NUMBER

W/35/124

9 DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

20 January 1989

10 DATE OF REVISION OF THE TEXT

1 March 2022