PROFESSIONAL INFORMATION

S4

1 NAME OF THE MEDICINE

^{123}I-SOLUTION, 74 MBq/ml solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

^{123}I-Solution contain iodine-123, obtainable from 74 MBq/ml.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

The ^{123}I-Solution is a clear solution containing radioactive material that is packed in a clear glass vial inside a lead pot. The ^{123}I-Solution is for injection or oral administration and only manufactured on order. The amount of iodine-123 and the volume of the solution is indicated on the label affixed to the lead pot and glass vial.

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

The ^{123}I-Solution can be administered orally or intravenously. The dosage varies from 5 to 370 MBq according to the amount prescribed for a specific diagnostic examination.

4.3 Contraindications

Sensitivity to iodine.

4.4 Special warnings and precautions for use

^{123}I-Solution is radioactive and should only be handled and administered by legally authorised personnel.

The ^{123}I-Solution is not recommended for pregnant patients. Since iodine-123 is excreted in human milk, formula feeding should be substituted for breastfeeding if ^{123}I-Solution 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 ^{123}I-Solution 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

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

Sodium chloride and

Water for injection

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 ^{123}I-Solution must be stored inside the lead pot in which it is packed. The solution 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

The ^{123}I-Solution is packed in a clear glass vial with a rubber stopper and aluminum seal/cap inside a lead pot. The label is affixed to the lead pot and glass vial. The lid of the lead pot is fitted with adhesive tape, on which the radioactivity marks appear.

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

Injection: S566 (Act 101 of 1965)

Oral solution: S567 (Act 101 of 1965)

9 DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

11 July 1984

10 DATE OF REVISION OF THE TEXT

1 March 2022