PROFESSIONAL INFORMATION

S4

1 NAME OF THE MEDICINE

^{123}I-mIBG INJECTION, 370 ± 25 % MBq (10,0 ± 25 % mCi) per 2 ml Injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

^{123}I-mIBG Injection contains 370 ± 25 % MBq (10,0 ± 25 % mCi) Iodine-123 (^{123}I-mIBG) per 2 ml.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

^{123}I-mIBG Injection is a clear, colourless or slightly yellow radioactive solution and is packed in a multi-dose glass vial in a lead pot. The ^{123}I-mIBG Injection is only manufactured on order. The amount of iodine-123 as well as the total volume of the injection in the glass vial is indicated on the label affixed to the glass vial and lead pot.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The ^{123}I-mIBG Injection is useful for scintigraphic diagnosis of abnormalities in the adrenal medulla and the heart muscle as well as for tumours of the neuroendocrine system (e.g. neuroblastoma or phaeochromocytoma).

4.2 Posology and method of administration

The dose for administration to adults is between 74 and 370 MBq or as prescribed for a specific diagnosis. The injection must be administered intravenously.

4.3 Contraindications

Sensitivity to iodine.

4.4 Special warnings and precautions for use

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

The ^{123}I-mIBG Injection is not recommended for pregnant patients. Since iodine-123 is excreted in human milk, formula feeding should be substituted for breastfeeding if ^{123}I-mIBG Injection 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-mIBG Injection 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 at normal levels of the diagnostic agent.

The absorbed radiation dose per unit activity (mGy/MBq) in different organs is as follows:

Organ	mGy/MBq	Organ	mGy/MBq
Adrenals	1.1E-02	Liver	7.1E-02
Bladder wall	7.0E-02	Ovaries	8.0E-03
Heart	1.1E-02	Testes	5.4E-03
Kidneys	1.4E-02		

(Annals of the ICRP Volume 18 No. 1-4 P330 1987).]

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.

Meta-iodobenzylguanidine (mIBG) is an analogue of the adrenergic blocking agent guanethidine, having uptake and storage mechanisms similar to those of norepinephrine. It has an affinity for chromaffin storage granules in adrenal medulla, myocardium and other tissues richly supplied with sympathetic nerves. (Annals of the ICRP Volume 18 No. 1-4 P329 1987).

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

Meta-iodobenzylguanidinesulphate (mIBG),

Ascorbic acid ($C_6H_8O_6$),

Copper nitrate ($Cu(NO_3)_2.3H_2O$),

Acetic acid ($C_2H_4O_2$),

Sodium bicarbonate ($NaHCO_3$),

Sodium chloride (NaCl) 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 multi-dose glass vial must be stored inside the lead pot in which it is packed.

The injection may be kept at room temperature (at or below 30 °C).

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

The ^{123}I-mIBG injection is filled into 5 ml clear glass vials with chloro-butyl rubber stoppers and aluminium caps. The vial is placed in a lead pot. The label is affixed to the glass vial and lead pot.

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

9 DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

2 July 1992

10 DATE OF REVISION OF THE TEXT

1 March 2022