

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS: S4

### <sup>123</sup>I-mIBG INJECTION

370 ± 25 % MBq (10,0 ± 25 % mCi) Iodine-123 (<sup>123</sup>I-mIBG) per 2 ml.

**Read all of this leaflet carefully before you are given <sup>123</sup>I-mIBG INJECTION.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

### What is in this leaflet

1. What <sup>123</sup>I-mIBG Injection is and what it is used for
2. What you need to know before you are given <sup>123</sup>I-mIBG Injection
3. How to take <sup>123</sup>I-mIBG Injection
4. Possible side effects
5. How to store <sup>123</sup>I-mIBG Injection
6. Contents of the pack and other information

#### **1 What <sup>123</sup>I-mIBG INJECTION is and what it is used for**

The <sup>123</sup>I-mIBG Injection is useful for scintigraphic (a diagnostic test in nuclear medicine) diagnosis of abnormalities in the adrenal medulla (the inner part of an adrenal gland) and the heart muscle as well as for tumours of the neuroendocrine system (e.g. neuroblastoma (a cancer that develops from immature nerve cells) or

phaeochromocytoma (rare, usually noncancerous (benign) tumor that develops in an adrenal gland)).

## **2 What you need to know before you are given <sup>123</sup>I-mIBG INJECTION**

**<sup>123</sup>I-mIBG Injection should not be administered to you:**

- if you are hypersensitive (allergic) to iodine or any of the other ingredients of <sup>123</sup>I-mIBG Injection (listed in section 6).

### **Warnings and precautions**

<sup>123</sup>I-mIBG Injection is radioactive and should only be handled and administered by legally authorised personnel.

Tell your doctor or health care provider before being given <sup>123</sup>I-mIBG Injection:

- if you are pregnant, as <sup>123</sup>I-mIBG Injection is not recommended for pregnant patients.
- If you are breastfeeding your baby since the iodine-123 in the <sup>123</sup>I-mIBG Injection is excreted in human milk. You will have to substitute breastfeeding with formula feeding.

### **Other medicines and <sup>123</sup>I-mIBG INJECTION**

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

### **Pregnancy and breastfeeding**

The safety of <sup>123</sup>I-mIBG Injection in pregnant women has not been established.

Since the iodine-123 in <sup>123</sup>I-mIBG Injection is excreted in breast milk, you should substitute breastfeeding with formula feeding if you are breastfeeding your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before being given this medicine.

### **Driving and using machines**

It is not always possible to predict to what extent <sup>123</sup>I-mIBG Injection may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which <sup>123</sup>I-mIBG Injection affects them.

### **3 How to take <sup>123</sup>I-mIBG INJECTION**

You will not be expected to give yourself <sup>123</sup>I-mIBG Injection. It will be given to you by a person who is qualified to do so.

Between 74 and 370 MBq of the <sup>123</sup>I-mIBG Injection will be administered intravenously before your specific diagnostic examination.

### **If you take more <sup>123</sup>I-mIBG INJECTION than you should**

Since a health care provider will administer <sup>123</sup>I-mIBG Injection, he or she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

## **If you forget to take <sup>123</sup>I-mIBG INJECTION**

Since a health care provider will administer <sup>123</sup>I-mIBG Injection, it is unlikely that the dose will be missed.

## **4 Possible side effects**

No side-effects are known at normal levels of the diagnostic agent.

However, should your general health worsen or if you experience any untoward effects while being given <sup>123</sup>I-mIBG Injection, please inform your doctor or health care provider.

## **Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of <sup>123</sup>I-mIBG Injection.

## **5 How to store <sup>123</sup>I-mIBG INJECTION**

You will not be expected to store <sup>123</sup>I-mIBG Injection yourself. It will be stored by a person who is qualified to do so.

## **6 Content of the pack and other information**

### **What <sup>123</sup>I-mIBG INJECTION contain**

- The active substance is iodine-123 (<sup>123</sup>I-mIBG), 370 ± 25 % MBq (10,0 ± 25 %) per 2 ml.

iThemba LABS  
<sup>123</sup>I-mIBG Injection  
370 ± 25 % MBq (10,0 ± 25 % mCi) Iodine-123

- The other ingredients are Meta-iodobenzylguanidinesulphate (mIBG), ascorbic acid (C<sub>6</sub>H<sub>8</sub>O<sub>6</sub>), copper nitrate (Cu(NO<sub>3</sub>)<sub>2</sub>·3H<sub>2</sub>O), acetic acid (C<sub>2</sub>H<sub>4</sub>O<sub>2</sub>), sodium bicarbonate (NaHCO<sub>3</sub>), sodium chloride (NaCl) and water for injection.

### **What <sup>123</sup>I-mIBG INJECTION looks like and contents of the pack**

<sup>123</sup>I-mIBG Injection is a clear, colourless or slightly yellow radioactive solution and 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 lead pot. The <sup>123</sup>I-mIBG Injection is only manufactured on order. The amount of iodine-123 as well as the total volume of the injection in the container is indicated on the label affixed to the lead pot.

### **Holder of Certificate of Registration**

iThemba LABS  
Old Faure Road  
FAURE  
Cape Town, 7131

### **This leaflet was last revised in**

March 2022

### **Registration number**

Z/35/75

iThemba LABS  
<sup>123</sup>I-mIBG Injection  
370 ± 25 % MBq (10,0 ± 25 % mCi) Iodine-123

### **Access to the corresponding Professional Information**

The PI will be made available to the treating physician at time of delivery of the <sup>123</sup>I-mIBG Injection.