

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS: S4

### <sup>123</sup>I-SOLUTION

Iodine-123, obtainable from 74 MBq/ml solution.

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

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

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

<sup>123</sup>I-SOLUTIONS are radiopharmaceuticals suitable for the diagnostic examination of your thyroid and the diagnosis of thyroid cancer.

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

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

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

### **Warnings and precautions**

<sup>123</sup>I-SOLUTION 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- SOLUTION:

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

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

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-SOLUTION in pregnant women has not been established. Since the iodine-123 in <sup>123</sup>I-SOLUTION 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-SOLUTION 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-SOLUTION affects them.

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

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

You will be given the prescribed amount of solution orally or intravenously before your diagnostic examination.

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

Since a health care provider will administer <sup>123</sup>I-SOLUTION, 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-SOLUTION**

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

#### **4 Possible side effects**

No side-effects are known.

However, should your general health worsen or if you experience any untoward effects while being given <sup>123</sup>I-SOLUTION, 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-SOLUTION.

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

You will not be expected to store <sup>123</sup>I-SOLUTION 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-SOLUTION contains**

- The active substance is iodine-123, obtainable from 74 MBq/ml.
- The other ingredients are sodium chloride and water for injection.

iThemba LABS  
<sup>123</sup>I-Solution  
74 MBq/ml Iodine-123 per solution

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

<sup>123</sup>I-SOLUTION is a clear solution containing radioactive material. The solution is packed in a clear glass vial inside a lead pot. The <sup>123</sup>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.

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

iThemba LABS  
Old Faure Road  
FAURE  
Cape Town, 7131

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

March 2022

### **Registration number**

Injection: S566 (Act 101 of 1965)

Oral solution: S567 (Act 101 of 1965)

### **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-Solution.