

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

¹²³I-CAPSULES

Iodine-123, obtainable from 5 to 370 MBq (\pm 10 %) per capsule.

Read all of this leaflet carefully before you are given ¹²³I-CAPSULES.

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

1 What ¹²³I-CAPSULES are and what it is used for

¹²³I-CAPSULES 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 ¹²³I- CAPSULES

¹²³I-CAPSULES should not be administered to you:

- if you are hypersensitive (allergic) to iodine or any of the other ingredients of ¹²³I-CAPSULES (listed in section 6).

Warnings and precautions

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

Tell your doctor or health care provider before being given ¹²³I-CAPSULES:

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

Other medicines and ¹²³I-CAPSULES

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 ¹²³I-CAPSULES in pregnant women has not been established. Since the iodine-123 in ¹²³I-CAPSULES 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 ¹²³I-CAPSULES 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 ¹²³I-CAPSULES affects them.

3 How to take ¹²³I-CAPSULES

You will not be expected to give yourself ¹²³I-CAPSULES. It will be given to you by a person who is qualified to do so.

You will be given one capsules orally before your diagnostic examination.

If you take more ¹²³I-CAPSULES than you should

Since a health care provider will administer ¹²³I-CAPSULES, he or she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to take ¹²³I-CAPSULES

Since a health care provider will administer ¹²³I-CAPSULES, 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 ¹²³I-CAPSULES, 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 ¹²³I-CAPSULES.

5 How to store ¹²³I-CAPSULES

You will not be expected to store ¹²³I-CAPSULES yourself. It will be stored by a person who is qualified to do so.

6 Content of the pack and other information

What ¹²³I-CAPSULES contain

- The active substance is iodine-123, obtainable from 5 to 370 MBq (\pm 10 %) per capsule.
- The other ingredients are anhydrous glucose (dextrose), size 1, clear and colourless gelatine capsules and 0,01 N sodium hydroxide solution.

iThemba LABS
¹²³I-Capsules
5 to 370 MBq (\pm 10%) Iodine-123 per capsule

What ¹²³I-CAPSULES look like and contents of the pack

¹²³I-CAPSULES are clear capsules containing radioactive material. One capsule is 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.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

The PI will be made available to the treating physician at time of delivery of the ¹²³I-Capsules.