Package leaflet: Information for the patient

MIBG (^{123}I) 74 MBq/mL solution for injection

iobenguane (^{123}I)

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your nuclear medicine doctor who will supervise the procedure.
- If you get any side effects, talk to your nuclear medicine doctor This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What MIBG (^{123}I) is and what it is used for

This medicine is a radiopharmaceutical product for **diagnostic use** only.

This medicine contains iobenguane (^{123}I), a radioactive substance which when injected, collects in certain organs such as the heart, the adrenal glands (glands which are located on the top of each kidney) and particular tumours.
The radioactive substance can be photographed from outside the body, using special cameras which take a scan. This scan shows where the radioactivity is inside the organ and the body. This gives the doctor valuable information about how that organ is working or where a tumour is located.

MIBG (^{123}I) is used in adults and children**:**
- to find particular tumours such as tumours of the adrenal glands and other hormone-producing tumours (so called neuroendocrine tumours),
- to find, plan and follow-up treatment of neuroblastomas (tumours in the nervous system, mostly affecting children),
- to estimate how much iobenguane (^{123}I) is absorbed by your body before starting a treatment with iobenguane,
- to examine how the adrenal glands or heart is working.

The use of MIBG (^{123}I) does involve exposure to small amounts of radioactivity. Your doctor and the nuclear medicine doctor have considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical outweighs the risk due to radiation.

2. What you need to know before MIBG (^{123}I) is used

MIBG (^{123}I) must not be used
- if you are allergic to iobenguane (123I) or any of the other ingredients of this medicine listed in section 6.

Warnings and precautions
Talk to your nuclear medicine doctor before you are given MIBG (^{123}I):
- if you are pregnant or believe you may be pregnant,
- if you are breastfeeding,
- if you have a reduced kidney function,
- if you have a disease which affects the nervous system such as Parkinson's and Parkinson-like diseases

Before administration of MIBG (^{123}I):
- your doctor will tell you to take another medicine containing non radioactive iodine before you are given MIBG (^{123}I). This medicine is to stop radioactivity building up in your thyroid gland.
- you should drink plenty of water before the start of the examination in order to urinate as often as possible during the first hours after the examination.
- your doctor may ask you to stop taking some medicines which can influence the examination (see paragraph "Other medicines and MIBG (^{123}I)")

Children and adolescents
Talk to your nuclear medicine doctor if you are under 18 years old.

Other medicines and MIBG (^{123}I)
Tell your nuclear medicine doctor who will supervise the procedure if you are taking, have recently taken or might take any other medicines since they may interfere with the interpretation of the images.

The following medicines or substances can particularly influence the examination:
- calcium-channel blockers (such as diltiazem, nifedipine, verapamil) used to treat high blood pressure and heart disorders
- tricyclic antidepressants (such as amitriptyline, imipramine) used to treat depressions
- medicines often used to treat blocked nose or cough (such as phenylephrine, ephedrine, phenylpropanolamine) reserpine and labetalol: medicines to treat high blood pressure medicines to treat mental disorders with active substance from the drug class "phenothiazines" such as, promethazine, levomepromazine, perphenazine
- cocaine (a drug of abuse)

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your nuclear medicine doctor for advice before you are given this medicine.
You must inform the nuclear medicine doctor before the administration of MIBG (^{123}I) if there is a possibility you might be pregnant, if you have missed your period or if you are breast-feeding.
When in doubt, it is important to consult your nuclear medicine doctor who will supervise the procedure.

- **If you are pregnant**
  The nuclear medicine doctor will **only** administer this product during pregnancy if a benefit is expected which will outweigh the risks.
- **If you are breast-feeding**
  The doctor may **delay the examination** until you no longer breast-feed. If this is not possible, your doctor will ask you to **stop breast-feeding for 3 days** and discard this milk, until the radioactivity is no longer in your body.

Driving and using machines
It is considered unlikely that MIBG (^{123}I) affect your ability to drive or to use machines.

MIBG (^{123}I) contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium- free'.

3. How MIBG (^{123}I) is used

There are strict laws on the use, handling and disposal of radiopharmaceutical products. MIBG (^{123}I) will only be used in special controlled areas. This product

will only be handled and given to you by people who are trained and qualified to use it safely. These persons will take special care for the safe use of this product and will keep you informed of their actions.

The nuclear medicine doctor supervising the procedure will decide on the quantity of MIBG (^{123}I) to be used in your case. It will be the smallest quantity necessary to get the desired information. The quantity to be administered usually recommended for an adult ranges from 110-400 MBq (Mega Becquerel, the unit used to express radioactivity).

Use in children and adolescents
In children and adolescents, the quantity to be administered will be adapted to the child's weight.

Administration of MIBG (^{123}I) and conduct of the procedure
MIBG (^{123}I) is administered by slow intravenous injection (injected into the vein over several minutes). You will be constantly monitored during the administration because a sudden and severe increase in blood pressure can occur if it is administered too fast (see section 4).
One injection is sufficient to conduct the test that your doctor needs. Following the MIBG (^{123}I) injection, you might be given a flush of sodium chloride injection in order to reduce the risk of pain at the injection site (see section 4).
Scans are taken between 15 minutes and 24 hours after the injection. Scans may be repeated one day later.

Duration of the procedure
Your nuclear medicine doctor will inform you about the usual duration of the procedure.

After administration of MIBG (^{123}I):
- You should drink and urinate frequently in order to eliminate the product from your body,
- Children and adolescents should continue to take the medicine to stop radioactivity building up in the thyroid gland, according to the nuclear medicine doctor's instructions.

The nuclear medicine doctor will inform you if you need to take any special precautions after receiving this medicine. Contact your nuclear medicine doctor if you have any questions.

If you have been given more MIBG (^{123}I) than you should
An overdose is unlikely because you will only receive a single dose of MIBG (^{123}I) precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the case of an overdose, you will receive the appropriate treatment.
In addition, the nuclear medicine doctor in charge of the procedure may recommend that you drink plenty of water and urinate frequently to remove the traces of radioactivity from your body.

Should you have any further question on the use of MIBG (^{123}I), please ask the nuclear medicine doctor who supervises the procedure.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects may occur with a frequency not known, during or immediately after injection, if administered too fast:
- fast or irregular heart beat
- difficulty breathing
- feeling warmer than usual,
- temporary high blood pressure.
  Signs of this may be headache and changes in your eyesight (visual disturbance).
- abdominal cramps and pain

These symptoms should disappear within one hour.

Other side effects which occur with a frequency not known:
- Allergic reactions with symptoms such as:
  - difficulty in breathing or dizziness,
  - redness,
  - itching, hives,
  - nausea, vomiting,
  - cold chills
- Headache
- Tingling or numbness in the hands and feet
- Local swelling, pain and other reactions at the injection site, skin and tissue damage in case of accidental leakage of the medicine into the surrounding tissue.

If you experience any of those, please refer immediately to your nuclear medicine doctor.
In case of an allergic reaction you will receive appropriate treatment.

This radiopharmaceutical will deliver low amounts of ionising radiation associated with the least risk of cancer or hereditary abnormalities.

Reporting of side effects
If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How MIBG (^{123}I) is stored

You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in appropriate premises. Storage of radiopharmaceuticals will be in accordance with national regulation on radioactive materials.

The following information is intended for the specialist only.
MIBG (^{123}I) must not be used after the expiry date which is stated on the label after "EXP".
MIBG (^{123}I) must not be used if there are visible signs of deterioration.

6. Contents of the pack and other information

What MIBG (^{123}I) contains
- The active substance is iobenguane (123I) as iobenguane sulfate.
  1 millilitre contains 74 MBq iobenguane (123I) and 0.5 mg iobenguane sulfate.
- The other ingredients are: citric acid monohydrate, sodium citrate dihydrate, water for injections.

What MIBG (^{123}I) looks like and contents of the pack
MIBG (^{123}I) is a clear, colourless or slightly yellow solution. It is packed in a 10 mL type I glass vial closed with a rubber stopper and sealed with an aluminium cap.
MIBG (^{123}I) is supplied in a vial containing 1 mL (74 MBq), 2 mL (148 MBq), 3 mL (222 MBq), 4 mL (296 MBq) or 5 mL (370 MBq).

Marketing Authorisation Holder and Manufacturer
Curium Netherlands B.V.
Westerduinweg 3
1755 LE Petten
The Netherlands

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The following information is intended for medical or healthcare professionals only:

The complete Summary of Product Characteristics (SmPC) of MIBG (^{123}I) is provided as a separate document in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical. Please refer to the SmPC of MIBG (^{123}I).