

MIBG (I123)

solution for injection

¹²³I as iobenguane and 3-iodobenzylguanidine sulphate

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What MIBG (I123) is and what it is used for
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1. What MIBG (I123) is and what it is used for

This medicine is for **diagnostic use** only.

MIBG (I123) is used through a scan to examine the:

- **location** of certain **tumours**
- **adrenal medulla**, part of the glands which are located on the top of each kidney
- **heart function**

This medicine contains a radioactive substance which when injected, collects in certain organs, such as the heart.

The radioactive substance can be photographed from outside the body, using special cameras which take a scan. This scan shows the distribution of radioactivity within the organ and body. This also gives the doctor valuable information about the structure and function of that organ.

2. Before you use MIBG (I123)

Do not use MIBG (I123)

if you are

- allergic (hypersensitive) to ¹²³I as iobenguane, 3-iodobenzyl-guanidine sulphate or any of the other ingredients. (For a list of other ingredients please see section 6)

Take special care with MIBG (I123)

This medicine does involve treatment with radioactivity. Your doctor will only give you this medicine if the benefit outweighs the risk.

MIBG (I123) is given by specialists, who will take responsibility for any necessary precautions.

Your doctor will inform you if you need to take any special precautions after using this medicine. Contact your doctor if you have any questions.

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Your doctor may recommend that you stop the following medicines before treatment:

- **diltiazem, nifedipine, verapamil** or similar substances used to treat high blood pressure and heart disorders
- **amitriptyline, imipramine** or similar substances used to treat depressions
- **phenylephrine, ephedrine, phenylpropanolamine** or similar substances often contained in nasal drops or sprays to treat blocked nose
- **reserpine**, a medicine to treat high blood pressure via the central nervous system
- **labetalol**, a medicine to reduce high blood pressure
- **medicines to treat mental disorders** with active substance from the drug class "phenothiazines" such as, promethazine, fluphenazine, chlorprothixine
- the local anaesthetic **cocaine**

Pregnancy and breast-feeding

- **Pregnancy**

Tell your doctor if you are pregnant or think you could be. Your doctor will **only** administer MIBG (I123) during **pregnancy if it is absolutely necessary**, as it could harm the unborn child.

- **Breast-feeding**

Tell your doctor if you are breast-feeding as he may **delay treatment** until breast-feeding is finished. He may also ask you to **stop breast-feeding for 3 days** and discard this milk, until the radioactivity is no longer in your body.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

MIBG (I123) is unlikely to impair the ability to drive and operate machinery.

Important information about some of the ingredients of MIBG (I123)

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'.

3. How to use MIBG (I123)

MIBG (I123) will always be used in a hospital or similar setting. It will only be administered to you by qualified people trained to handle radioactive material safely.

Your doctor will decide the MIBG (I123) amount to be used. The dose administered will depend on the procedure. The lowest dose possible will be used to produce adequate images.

The usual dose is:

Approximate dose for **adults** and the elderly is:

- 80 - 200 MBq injected into a **vein** over several minutes.

MBq is the unit used to measure radioactivity, and defines the activity of a quantity of radioactive material.

Children under 18 years

Lower doses are used for children according to their body weight.

Method of use

One injection is usually sufficient; administered over at least one minute.

You will receive a medicine to reduce the thyroid uptake, one to two days before injection until three days after injection.

Scans are usually taken on the day after injection and may be repeated one day later.

Drink and urinate as much as possible before and after treatment. This will prevent active substance gathering in the bladder.

If more MIBG (I123) is given than it should

It is unlikely that overdose will occur as this medicine is given under control by a doctor. However, if this happens you will receive appropriate treatment from your doctor.

Drinking as much as possible, such as water, will help remove the radioactive substance more quickly.

If you have any further questions on the use of this product, ask your doctor.

4. Possible side effects

Like all medicines, MIBG (I123) can cause side effects, although not everybody gets them.

Side effects can occur with the following frequencies:

rare, occurs in 1 to 10 per 10,000 users

- allergic reactions with signs such as:

- flushes
- swellings similar to after insect stings
- nausea
- cold chills

Hospital staff will treat these reactions, if they occur.

- The following side effects may also occur during or immediately after injection, if MIBG (I123) is administered too fast:

- palpitations
- difficulty breathing
- heat sensations
- temporary high blood pressure
- abdominal cramps

These symptoms should disappear within one hour.

frequency unknown, from the data available

- cancer or hereditary defects are linked to radiation exposure
However, the risk is very low as low doses are used in this investigation.

Reporting of side effects

If you get any side effects, talk to your Nuclear medicine doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also

5. How to store MIBG (I123)

Keep out of the reach and sight of children.

Do not use MIBG (I123) after the expiry date stated on the label.

Hospital staff will ensure that the product is correctly stored below 25°C.

After opening the vial for the first time it should be stored between 2-8°C and the solution must be used within 8 hours.

6. Further information

What MIBG (I123) contains

- The active substances are: ¹²³I as iobenguane and 3-iodobenzylguanidine sulphate
One millilitre of MIBG (I123) contains 74 MBq iodine-123 and 0.5 mg 3-iodobenzylguanidine sulphate.
- The other ingredients are: citric acid monohydrate, sodium citrate dihydrate, water for injections

What MIBG (I123) looks like and contents of the pack

MIBG (I123) is a clear, colourless solution. It is packaged in type 1 Ph.Eur glass vials closed with a bromobutyl rubber stopper and sealed with an aluminium crimp cap.

MIBG (I123) is supplied in one vial containing:

- 74 MBq (1 ml),
- 148 MBq (2 ml),
- 222 MBq (3 ml),
- 296 MBq (4 ml) or
- 370 MBq (5 ml).

Marketing Authorisation Holder and Manufacturer

Mallinckrodt Medical B.V.
Westerduinweg 3
1755 LE Petten
The Netherlands

This leaflet was last approved in 09/2015

report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace,
IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website:
www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can
help provide more information on the safety of this medicine..