The medicinal product is a radioactive injection for intravenous administration containing meta-iodoobenzylguanidine labelled with $^{131}$I.

**Specification:** Ph. Hip. VII. 1. 165/B.39.5.

**Symbol indicating the strengths:** + (single cross), strong action

**Manufacturer:** Institute of Isotopes Co. Ltd. Budapest, Hungary, H-1121 Ronkoly-Thege Miklos 20-29.

**NAME OF THE MEDICINAL PRODUCT**

- **$[^{131}I]$-meta-Iodobenzylguanidine injection ($[^{131}I]$-MIBG)** for therapeutic purposes

**Quantity per volume unit**

- **Active ingredient**
  - $[^{131}I]$-meta-iodoobenzylguanidine sulphate
    - 333-410 MBq/ml contains not more than 0.60 mg/kg of the labelled substance in 10 ml solution

- **Catalyst of labelling with radiodiode**
  - Local, lesion-specific radiation therapeutic effect

- **Compositions**
  - Component of Walpole’s buffer
  - Component of Sodium acetate
  - Catalyst of labelling with radiodiode
  - Component of MIBG
  - Component of Acetic acid

- **Water for injection**
  - 1.0 g/ml

**Physical half life:**

- 8.0 days

**Energy and intensity of the emitted beta particles**

- 81.7 % 164 keV
- 81.7 % 284 keV
- 503 keV 325 keV
- 325 keV 636 keV
- 636 keV 722 keV
- 722 keV 1316 keV
- 1316 keV 2.3 eV

**RELATIVE CONTRAINDICATIONS**

- at the age below 18 years, except the indication of neuroblastoma.

**Dosage forms**

- Injectable sterile solution.

**CLINICAL PARTICULARS**

- **Therapeutic indications**
  - Local, lesion-specific treatment of neuroendocrine tumours, especially:
    - pheochromocytoma
    - neuroblastoma
    - paraganglioma
    - medullary thyroid carcinoma
    - carcinosad

**Method of examination**

- The recommended individual dose is 3.3–4.1 GBq.
- To prevent the uptake of the free radiodiode evolving in vivo, the blockade of thyroid is recommended before radioiodine therapy.

**Posology**

- The recommended dose is 3.3–4.1 GBq. Add the MIBG injection (volume 10 ml) to 90 ml of 5% glucose solution and administer this 100 ml volume to the patient as slow infusion.

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- The recommended dose is 3.3–4.1 GBq. Add the MIBG injection (volume 10 ml) to 90 ml of 5% glucose solution and administer this 100 ml volume to the patient as slow infusion.

**Method of administration**

- The method of examination should not be used concomitant and it is advised to stop their administration in the pre-treatment period.

**Pharmacodynamic properties**

- Hormones produced by the adrenal medulla, which contains the MIBG, can be used to treat in the neoplastic condition of the adrenal gland.

**Pharmacological properties**

- The highest administered quantity of MIBG is 6 mg and the administered $^{131}$I-MIBG is 16% as metabolised to meta-iodine hippuric acid and 2% as free $^{131}$I-MIBG leaves the body in the urine: 82% as unchanged $^{131}$I-MIBG, 16% as metabolised to meta-iodine hippuric acid and 2% as free $^{131}$I-MIBG.
WHAT [131I]ODINE-MIBG INJECTION IS AND WHAT IT IS USED FOR

[131I]ODINE-MIBG INJECTION is a radiopharmaceutical preparation which has been used for the local lesion-specific treatment of neuroendocrine tumours. This product can be utilized only at the departments of nuclear medicine.

[131I]ODINE-MIBG INJECTION is a colourless solution. This therapeutic agent is such a product, which is administered intravenously into the human body. The active ingredient of the injection accumulates in cells, which are in functional relationship with the adrenal medulla, and binds to the neuroendocrine receptors of the myocardium. It appears in the adrenal gland 24 hour after administration afterwards in the neuroendocrine tumours and metastasis where it can take therapeutic effect.

What [131I]ODINE-MIBG INJECTION is used for?

After [131I]ODINE-MIBG INJECTION is administered intravenously into the human body it reaches the neuroendocrine tumours via the blood circulation. This medicinal product is for therapeutic use only.

2 BEFORE YOU ARE GIVEN [131I]ODINE-MIBG INJECTION

2.1 Special warnings and special precautions

Comply with the instructions of your physician both before and after the examination. That fraction of the radioisotope, which is not bounded, leaves your body in the urine. Flush your urine with abundant quantity of water two or three times and wash your hands thoroughly for several days after administration of the injection. Be careful not to drip the material on other places than the WC. Change your underwear if it becomes contaminated and wash it separately by using abundant quantities of water.

2.2 Pregnancy and breast-feeding

Please inform your doctor if you are pregnant or are breast-feeding an infant. Do not use this medicinal product in these cases.

2.3 Paediatrics

This medicinal product must not be administered to patients below 18 years of age, except the indication of neoplasms.

2.4 Other cases in which this product is inapplicable

This medicinal product must not be administered if the patient does not provide a written consent of being examined.

2.5 Driving and using machines

You can drive and use machines. In occurrence of unexpected side effects the ability to drive and the aptitude to work amidst accident risk are to be reconsidered.

2.6 Important information about [131I]ODINE-MIBG INJECTION

Purpose of administration of [131I]ODINE-MIBG INJECTION is to decrease the radiation exposure of the whole body, to achieve longer therapeutic effect in case of benign and malignant tumours. YOU SHOULD CHECK WITH YOUR DOCTOR BEFORE THE ADMINISTRATION OF THIS PRODUCT IF YOU ARE UNSURE. TAKING OTHER MEDICINES:

Calcium channel blocking agents, labetalol, reserpine, tricyclic anti-depressants, pirenidone and cetodione may inhibit the uptake of MIBG. These drugs should not be used concomitantly and it is advised to stop their administration in the pre-treatment period.

3 HOW IS [131I]ODINE-MIBG INJECTION IS GIVEN

[131I]ODINE-MIBG INJECTION is administered intravenously. The dose is a function of the severity of your disease and is determined by your physician.

What to do in case of overdose?

Use of [131I]ODINE-MIBG INJECTION is strictly controlled thus the probability of overdose is low. However, it has been clearly proven by experiments that administration of excess injection does not bring about damaging effects. There are strict rules and regulations referring to the handling, shipping and storage of radioactive materials. Therefore, [131I]ODINE-MIBG INJECTION can only be used in designated clinical settings or institutes. Only people who are specialised to handle, use and annihilate this injection and are properly trained to manage radioactive materials can deal with this medicine. These people instruct you about the precautions and warnings. Comply with their instructions.

4 POSSIBLE SIDE EFFECTS OF [131I]ODINE-MIBG INJECTION

[131I]ODINE-MIBG INJECTION can have side effects if it is administered suddenly. Rapid administration can result in blood pressure increase, allergic symptoms, flush or asthmatic spasms. If you notice any side effects, please inform your doctor.

5 STORING [131I]ODINE-MIBG INJECTION

Staff of the hospital is responsible for the storage of the product and for avoidance of administering expired product. Keep out of the reach and sight of children and people who are not allowed by the management to transport this product. Freeze and store at -18 ºC. Observe the regulations referring to radiation protection. Storage conditions and expiry date is indicated on the label of the vial containing the drug.

This leaflet was prepared on 30.05.2003.

Additional information

The information given above is a brief summary. For further information about [131I]ODINE-MIBG INJECTION ask your doctor.

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder (Institute of Isotopes Co. Ltd.)

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