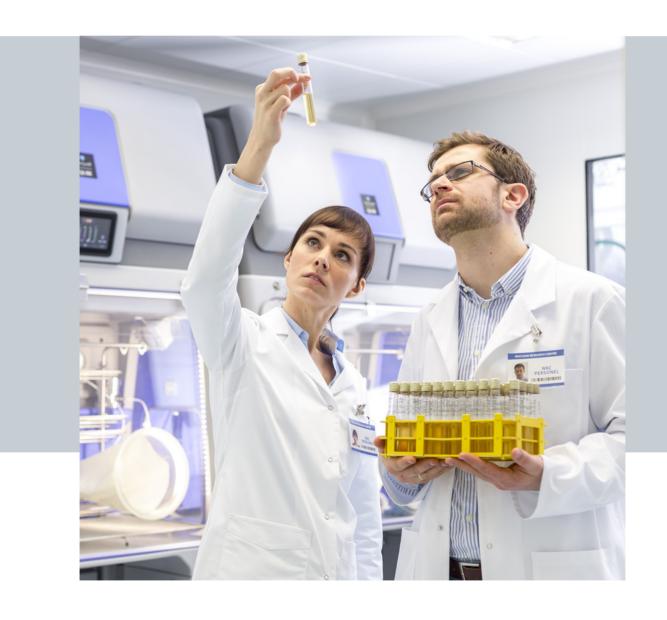


# Radiopharmaceuticals



Distributeur exclusif



# Sodium iodide Na<sup>131</sup>I

# capsules for therapeutic use. Hard capsules, 37-5500 MBq

Natrii iodidi (131 l) capsulae ad usum therapeuticum

#### Qualitative and quantitative composition:

Single hard capsule contains sodium iodide (131) in the radioactivity range [37-5500 MBq]. Iodine-131 is obtained by neutron irradiation of tellurium in a nuclear reactor or by extraction from uranium fission products. Iodine-131 has a half-life of 8.02 days. It decays to stable xenon-131, by emission of gamma radiations of 365 keV (81.7%), 637 keV (7.2%) and 284 keV (6.1%) and beta radiation of maximal energy of 606 keV.

### **Excipients**:

Sodium carbonate, sodium hydrogen carbonate, disodium hydrogen phosphate dihydrate, sodium thiosulphate pentahydrate, hard gelatin capsule.

#### **■** Indications:

This product is used in the treatment of:

▶ thyroid nodular goitre, hyperthyroidism in the Graves-Basedow's disease, autonomic nodule and the toxic multinodular goitre. It is used for the thyroid residue ablation after surgery of differentiated thyroid tumours and in the treatment of iodine-accumulating metastases.

#### Posology and method of administration:

Sodium iodide Na<sup>131</sup>I POLATOM, capsules for therapeutic use is a medicinal product with varying radioactivity, for oral administration.

The recommended therapeutic dose is a matter for clinical judgement. This dose should be established individually for each patient.

(for detailed information see SmPC)

## ■ Calibration:

7 days

- Radionuclidic purity:
- ≥ 99.9%
- Radiochemical purity:
- ≥ 95%
- **Expiration**:

21 days from the the date of manufacture

#### Storage:

at temperature below 25°C

#### ■ Package:

The polypropylene vial closed with a polypropylene stopper containing iodine absorber and placed in a shielding lead container. Every vial contains a single capsule. Each container is accompanied by a separate polypropylene applicator for capsule administration.

code: MI-4T



Marketing authorization:

Poland: Jodek sodu Na<sup>131</sup>I POLATOM

kapsułki do terapii

Belarus: НАТРИЯ ИОДИД Na<sup>131</sup>I ПОЛАТОМ

капсулы для терапии

Colombia: Yoduro sodico-131 capsulas

Costa Rica: Yoduro de sodio Na 131 I POLATOM

capsulas

South Korea: Thyrokey P therapeutic

sodium iodide I-131 capsule

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