



Radiopharmaceuticals



CYCLOPHARMA

Distributeur exclusif



Spécialisé en Médecine Nucléaire et Imagerie Médicale

Sodium iodide Na¹³¹I

capsules for therapeutic use. Hard capsules, 37–5500 MBq

Natrii iodidi (¹³¹I) capsulae ad usum therapeuticum

code: MI-4T

■ Qualitative and quantitative composition:

Single hard capsule contains sodium iodide (¹³¹I) 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 Na¹³¹I 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.



Marketing authorization:

Poland: Jodek sodu Na¹³¹I POLATOM kapsułki do terapii

Belarus: НАТРИЯ ИОДИД Na¹³¹I ПОЛАТОМ капсулы для терапии

Colombia: Yoduro sodico-131 capsulas

Costa Rica: Yoduro de sodio Na¹³¹I POLATOM capsulas

South Korea: Thyrokey P therapeutic sodium iodide I-131 capsule

Contact:

Export Department +48 22 273 1820

email: export@polatom.pl