

^{68}Ga i beredningsrum

Bakgrund

- Ersätta ^{111}In Octreotid med ^{68}Ga -DOTA-PET
 - ^{68}Ga DOTATOC
 - ^{68}Ga DOTATATE
 - ^{68}Ga DOTANOC
- Framtiden ^{68}Ga -PSMA...
- Idag undersöks RÖL´s patienter i Uppsala

Vad behöver för grejer?

- Gallium
 - ^{68}Ga generator
 - Cyklotron
- Märka ^{68}Ga med lämplig substans
 - Syntesmodul
 - Kit
- Kvalitetskontroller
- Strålskydd

Vad finns det för generatorer?



Eckert & Ziegler Gallipharm
Marknadsföringstillstånd
Leveranstid 18 månader
SmPC för SomaKit



IRE GalliEo
Marknadsföringstillstånd Juli 2018
Leveranstid ca 12v
Ny SmPC för SomaKit på gång...



Eckert & Ziegler IGG100
Ej marknadsföringstillstånd
Används av några sjukhus i
sverige.



ITG
Ej marknadsföringstillstånd

Kemi



Syntesmodul

Krävs tillverkningstillstånd

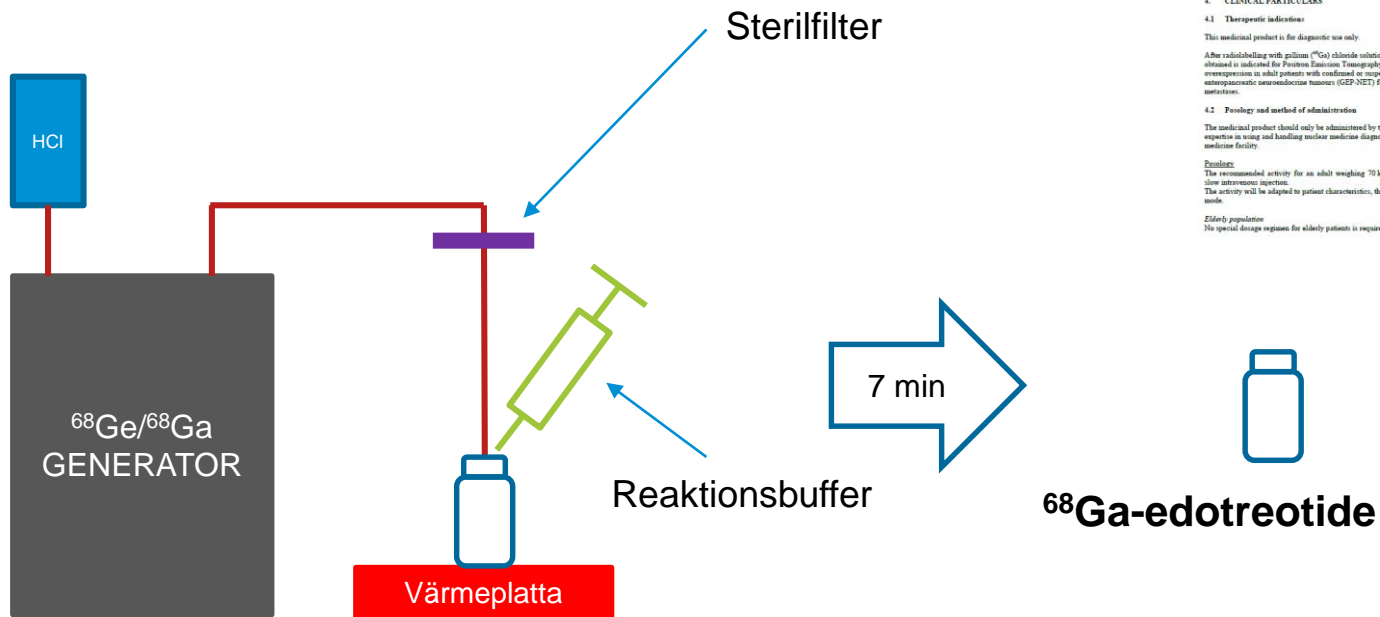


Kit-beredning

SOMAKIT-TOC

Marknadsföringstillstånd

Hur går det till?



▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

1. NAME OF THE MEDICINAL PRODUCT

SomaGo TOC 40 microgramm kit for radiopharmaceutical preparation

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial of powder contains 40 microgramm of edotreotide.

The radionuclide is not part of the kit.

Edotreotide with known effect:

The vial of buffer contains approximately 32.5 mg of sodium.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Kit for radiopharmaceutical preparation containing:

- Powder for solution for injection: the vial contains a white lyophilized powder.
- Reaction buffer: the vial contains a clear, colorless solution.

For radiolabelling with gallium (^{68}Ga) chloride solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicinal product is for diagnostic use only.

After radiolabelling with gallium (^{68}Ga) chloride solution, the solution of gallium (^{68}Ga) edotreotide obtained is indicated for Positron Emission Tomography (PET) imaging of somatostatin receptor overexpression in adult patients with confirmed or suspected well-differentiated gastro-enteropancreatic neuroendocrine tumours (GEP-NET) for localising primary tumours and their metastases.

4.2 Posology and method of administration

The medicinal product should only be administered by trained healthcare professionals with technical expertise in using and handling nuclear medicine diagnostic agents and only in a designated nuclear medicine facility.

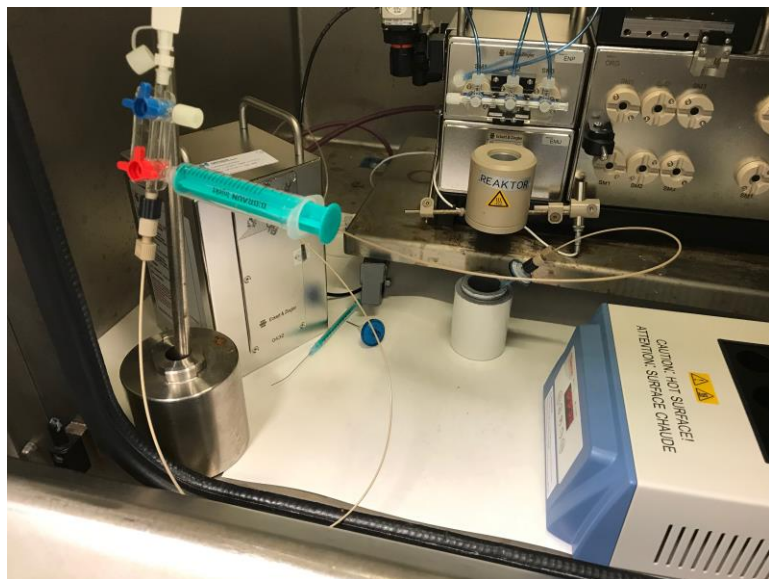
Posology

The recommended activity for an adult weighing 70 kg is 100 to 200 MBq, administered by direct slow intravenous injection.
The activity will be adapted to patient characteristics, the type of PET camera used and acquisition mode.

Elderly population

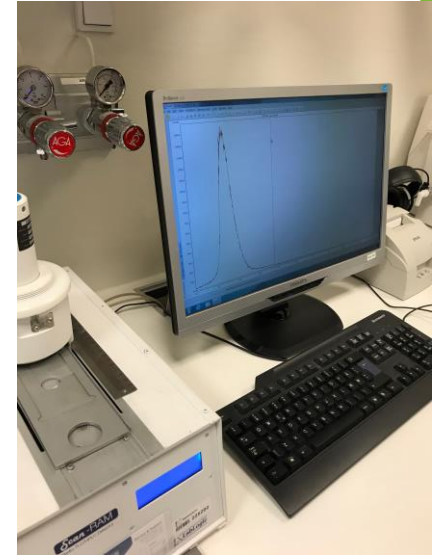
No special dosage regimen for elderly patients is required.

SomaKit på Rigshospitalet



Kvalitetskontroll

- pH-värde
- Inmärkning med r-TLC



Strålskydd

- Vi fick möjlighet att köpa en begagnad hotcell från Göteborg... men...
- Upphandlar just nu en MSC II säkerhetsbänk med 50 mm bly

