Sogacin®/TOCscan®
Gallium (^{68}Ga) edotreotide

MAH: Isotope Technology Garching (ITG)
Commercialised in Austria and France by IASON GmbH

Marketing Authorisation countries

Countries	1st Marketing Authorisation	Marketing Authorisation Number	Marketing Authorisation Holder's Name
France	01.07.2016	34009 550 236 9 2 (25)	SOGACIN®
Austria	07.12.2016	437334 (25)	Sogacin®
Germany	09.12.2016	98351.00.00 (25)	TOCscan®

CLINICAL PARTICULARS

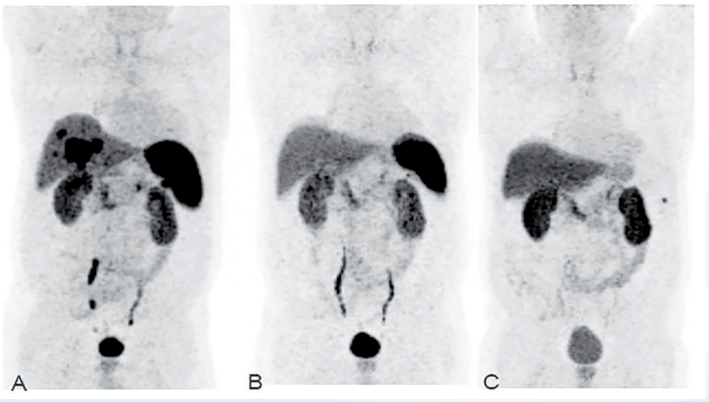
This medicinal product is for diagnostic use only.

Sogacin®/TOCscan® binds specifically to somatostatin receptors.
Sogacin®/TOCscan® is indicated for use with positron emission tomography (PET).
Sogacin®/TOCscan® is used for imaging in patients undergoing oncologic diagnostic procedures describing functions or diseases where enhanced somatostatin receptors expression of specific organs or tissues is the diagnostic target.

The following indications have been particularly documented:

- Detection of the primary occult neuroendocrine tumour when a metastasis of neuroendocrine tumour has been demonstrated or when the serum concentration of a specific marker is increased,
- Characterisation of bronchial mass as neuroendocrine tumour when other diagnostic modalities have not been conclusive,
- Characterisation, initial staging, detection in case of biochemical recurrence and restaging of neuroendocrine tumours of the foregut, including in the thymus or the bronchi,
- Characterisation, initial staging, detection in case of biochemical recurrence and restaging of neuroendocrine tumours of the midgut, when 6-fluoro-(^{18}F)-L-dihydroxyphenylalanine is not available or when PET with 6-fluoro-(^{18}F)-L-dihydroxyphenylalanine is non-conclusive,
- As an adjunct to anatomic imaging in pre-therapeutic evaluation of meningeoma.

Tumours which do not bear somatostatin receptors will not be visualised with Sogacin®/ TOCscan®.



Sogacin®/ TOCscan® PET/CT scan:

(A) Sogacin®/ TOCscan® PET/CT scan of patient with insulinoma of the pancreatic tail and multiple liver metastases.

(B) Sogacin®/TOCscan® PET/CT scan of the same patient did not show pathological tracer uptake in the body after three applications of ^{90}Y-DOTA-TOC. In addition to the good therapeutic response, laparoscopic resection of the pancreatic tail, one liver segment and splenectomy were performed.

(C) After 1.5 year Sogacin®/TOCscan® PET/CT scan showed no residual disease.

Published in World Journal of Gastroenterology, 2014.

Courtesy of: *Prim. ao. Univ.-Prof. Mag. Dr. Michael Gabriel, Institute of Nuclear and Endocrinology, Kepler University Clinic, MC3, Linz, Austria*

2. Posology and method of administration
Posology

Adults and elderly
The recommended activity for an adult weighing 70 kg is 100 to 200 MBq (the activity will be adapted to the body mass, the type of camera used, PET or PET/CT, and acquisition mode), administered by direct intravenous injection.

Patients with renal impairment
Careful consideration of the activity to be administered is required since an increased radiation exposure is possible in these patients.

Paediatric population
There is limited clinical data on the safety and efficacy of this product in the under 18 year old patient. The use in children and adolescents has to be considered carefully, based upon clinical needs and assessing the risk/benefit ratio in this patient group. The activities to be administered to children and adolescents may be calculated according to the recommendations of the European Association of Nuclear Medicine (EANM) for paediatric task group Dosage Card; the activity administered to children and to adolescents may be calculated by multiplying a recommended activity for an adult (for calculation purposes) by the multiples given in the table below.

$A[MBq]_{Administered}$ =
Recommended Activity for an adult × Multiple

Weight [kg]	Multiple	Weight [kg]	Multiple	Weight [kg]	Multiple
3	0.1	22	0.50	42	0.78
4	0.14	24	0.53	44	0.80
6	0.19	26	0.56	46	0.82
8	0.23	28	0.58	48	0.85
10	0.27	30	0.62	50	0.88
12	0.32	32	0.65	52-54	0.90
14	0.36	34	0.68	56-58	0.92
16	0.40	36	0.71	60-62	0.96
18	0.44	38	0.73	64-66	0.98
20	0.46	40	0.76	68	0.99

Method of administration
For intravenous use.
The injection of Sogacin®/TOCscan® must be intravenous in order to avoid irradiation as a result of local extravasation, as well as imaging artefacts. The injection site should be selected remote from the pathological areas to be examined in priority, usually in the forearm.
For multidose use.

Precautions to be taken before handling or administration of the medicinal product
For patient preparation, see section 4.

The activity of Sogacin®/TOCscan® has to be measured with an activimeter immediately prior to injection.

Image acquisition
Image acquisition starts between 45 and 60 minutes after injection. If required, repeated gallium (^{68}Ga) edotreotide PET examinations can be reiterated within a short period of time.

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3. Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Pregnancy (see section 6)

4. Special warnings and precautions for use

Individual benefit/risk justification
For each patient, the radiation exposure must be justifiable by the likely benefit. The activity administered should in every case be as low as reasonably achievable in order to obtain the required diagnostic information.

Diagnostic efficacy of gallium (^{68}Ga) edotrotide has not been demonstrated in the pretherapeutic dosimetry evaluation prior to peptide receptor radionuclide therapy targeting somatostatin receptors.

Renal impairment
Careful consideration of the benefit risk ratio in these patients is required since an increased radiation exposure is possible.

Paediatric population
For information on the use in paediatric population, see section 2.

Patient preparation
Administration of Sogacin®/TOCscan® does not require that the patient be fasting.
In order to obtain images of best quality and to reduce the radiation exposure of the bladder, patients should be encouraged to drink sufficient amounts and to empty their bladder prior to and after the PET examination.

Interpretation of Sogacin® / TOCscan® images
PET images with Sogacin®/TOCscan® reflect the density of somatostatin receptors.
The image interpretation must take into account the normal biodistribution of the radiopharmaceutical. Sogacin®/TOCscan® is constantly taken-up by the normal pituitary gland, thyroid gland, liver, spleen, kidneys and adrenals. Sogacin®/TOCscan® may also be variably taken-up by the normal posterior part of the head of the pancreas (uncinate process).
Some pathological conditions (like subacute inflammation, breast cancer, lymphoma) can also show a variable uptake of Sogacin®/TOCscan®.
Inversely, tumours which do not bear somatostatin receptors will not be visualised with Sogacin®/TOCscan®.
In case of Cushing syndrome, a long-term exposure to endogenous hypercortisolism may down regulate somatostatin receptor expression and negatively influence the results of somatostatin receptor imaging with gallium (^{68}Ga) edotreotide. In patients with Cushing syndrome, the normalisation of hypercortisolism should be considered before performing PET with gallium (^{68}Ga) edotreotide.

An increased uptake of gallium (^{68}Ga) edotreotide is not specific for GEP-NET. Positive results require evaluating the possibility that another disease, characterised by high local somatostatin receptor concentrations, may be present. For example, an increase in somatostatin receptor density can also occur in the following pathological conditions: subacute inflammations (areas of lymphocyte concentrations), thyroid diseases (e.g. autonomous thyroid nodule and Hashimoto's thyroiditis), tumours of the pituitary gland, neoplasms of the lungs (small-cell carcinoma), meningiomas, mammary carcinomas, lympho-proliferative disease (e.g. Hodgkin's and non-Hodgkin lymphomas) and tumours arising from tissue embryologically derived from the neural crest (e.g. paragangliomas, medullary thyroid carcinomas, neuroblastomas, pheochromocytomas).
In patients after splenectomy, splenosis should also be considered as a source of false positive results of imaging with gallium (^{68}Ga) edotreotide.
Concomitant use of somatostatin analogues
It is preferable to perform imaging with gallium (^{68}Ga) edotreotide the day(s) before the next administration of a somatostatin analogue. See section 5.

After the procedure
Close contact with infants and pregnant women should be restricted during the initial 8 hours following the injection.

Specific warnings
Depending on the time when you administer the injection, the content of sodium given to the patient may in some cases be greater than 1 mmol ***(23 mg)***. This should be taken into account in patients on low sodium diet. This medicinal product contains 7.4% ethanol, i.e. up to 0.6 g per maximum volume of 10 mL. This amount will produce a blood alcohol concentration of 0.015 g/L (1.5 mg/100 mL) for an adult weighing 70 kg. This is equivalent to 15 mL of beer or 6 mL of wine per maximum dose.

This should be taken into account in patients suffering from alcoholism, breast-feeding women, children and high-risk groups such as patients with liver disease or epilepsy.
Precautions with respect to environmental hazard are in section 6.6.
The maximum volume to be administered to a patient should not exceed 10 mL.

5. Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.
Somatostatin analogues seem not to compete with Sogacin®/TOCscan® for binding to somatostatin receptors in target cells.

However it is recommended to avoid concurrent treatment with somatostatin analogues with a long half-life for a few days before PET/CT with Sogacin®/TOCscan®. Somatostatin analogues with a short half-life may be used up to 24 hours before PET/CT with Sogacin®/TOCscan®.

6. Fertility, pregnancy and lactation

Women of childbearing potential
When an administration of radiopharmaceuticals to a woman of childbearing potential is intended, it is important to determine whether or not she is pregnant. Any woman who has missed a period should be assumed to be pregnant until proven otherwise. If in doubt about her potential pregnancy (if the woman has missed a period, if the period is very irre-gular, etc.), alternative techniques not using ionising radiation (if there are any) should be offered to the patient.

Pregnancy
The use of Sogacin®/TOCscan® is contraindicated in pregnant women due to the radiation exposure to the foetus (see section 3).

Breastfeeding
Before administering radiopharmaceuticals to a mother who is breastfeeding, consideration should be given to the possibility of delaying the administration of radionuclide until the mother has ceased breastfeeding, and to what is the most appropriate choice of radiopharmaceuticals, bearing in mind the secretion of activity in breast milk. If the administration is considered necessary, breastfeeding should be interrupted for 8 hours and the expressed feeds discarded.

Close contact with infants should be restricted during this period.

Fertility
No studies on fertility have been performed.

7. Effects on ability to drive and use machines

Not relevant.

8. Undesirable effects

Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. As the effective dose is 4.4 mSv in men and 5 mSv in women when the maximal recommended activity of 200 MBq is administered these adverse reactions are expected to occur with a low probability.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reaction via the national reporting system.

9. Overdose

In the event of administration of a radiation overdose with Sogacin®/TOCscan® the absorbed dose to the patient should be reduced where possible by increasing the elimination of the radionuclide from the body by forced diuresis and frequent bladder voiding. It might be helpful to estimate the effective dose that was applied.

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