PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Sogacin 20 MBq/mL solution for injection
Gallium (^{68}Ga) edotreotide

Read all of this leaflet carefully before you are administered this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your nuclear medicine doctor who will supervise the procedure.
- If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Sogacin is and what it is used for

Pharmacotherapeutic group – ATC code: Diagnostic radiopharmaceuticals, ATC code: V09IX09.

This medicine is a radiopharmaceutical product for diagnostic use only.

Sogacin is used for diagnosis in Positron Emission Tomography (PET) examinations and is administered prior to such an examination.

The radioactive substance in Sogacin is detected by PET and is shown as a picture.

Positron Emission Tomography is an imaging technology used in nuclear medicine that produces pictures of cross-sections of living organisms. It works with a minute amount of radioactive pharmaceutical to produce quantitative and precise images of specific metabolic processes in the body. This examination is carried out to help decide on how to treat the illness you are suffering from or you are suspected of suffering from.

The use of Sogacin does involve exposure to small amounts of radioactivity. Your nuclear medicine doctor has considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical outweighs the risk due to radiation.

2. What you need to know before Sogacin is administered

Sogacin must not be used:
- if you are allergic to gallium (^{68}Ga) edotreotide or any of the other ingredients of this medicine (listed in section 6),
- if you are pregnant.

Warnings and precautions
Take special care with Sogacin.
Talk to your nuclear medicine doctor before you are given Sogacin:
- if you have others medical conditions, such as high level of cortisol in the body (Cushing syndrome), inflammation, thyroid disease, other type of tumour (of pituitary gland, lung, brain, breast, immune system, thyroid, adrenal gland or others) or disease of spleen (including previous trauma or surgery involving the spleen). Such conditions may be visible and affect the interpretation of the images. Your doctor may therefore perform additional scans and tests to confirm the findings on Gallium (^{68}Ga) edotreotide imaging.

- if you have been recently vaccinated. Enlarged lymph nodes due to vaccination may become visible during gallium (^{68}Ga) edotreotide imaging.
- if you are pregnant or believe you may be pregnant.
- if you are breast-feeding.

Before administration of Sogacin you should:
- drink plenty of water and be well hydrated before the start of the examination in order to urinate as often as possible during the first hours after the study.

Children and adolescents
Talk to your nuclear medicine doctor if you are under 18 years old.

Other medicines and Sogacin
Tell your nuclear medicine doctor if you are taking, have recently taken or might take any other medicines, since they may interfere with the interpretation of the images :
- Somatostatin analogues

Sogacin with food and drink
You do not need to be fasting before the examination. You should drink plenty of water.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your nuclear medicine doctor for advice before you are given this medicine.

You must inform the nuclear medicine doctor before the administration of Sogacin if there is a possibility you might be pregnant, if you have missed your period or if you are breast-feeding.
When in doubt, it is important to consult your nuclear medicine doctor who will supervise the procedure.

If you are pregnant:
Sogacin must not be administered to you.

If you are breast-feeding:
Breast milk may be drawn off before injection and stored for subsequent use. Breast-feeding should be stopped for at least 8 hours after the injection. Any milk produced during this period should be discarded.
Please ask your nuclear medicine doctor when you can resume breast-feeding.

Driving and using machines
It is considered unlikely that Sogacin will affect your ability to drive or to use machines.

Sogacin contains sodium and ethanol
This medicine contains up to 35 mg sodium (main component of cooking/table salt) per maximum dose (10 mL). This is equivalent to 1.8 % of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains up to 584 mg alcohol (ethanol) per maximum dose (10 mL), equivalent to 5.8 mg/mL (7.4 % v/v). The amount in 10 mL of this medicine is equivalent to 15 mL beer or 6 mL wine.

The amount of alcohol in this medicine is not likely to have an effect in adults and adolescents, and its effects in children are not likely to be noticeable. It may have some effects in younger children, for example feeling sleepy. The alcohol in this medicine may alter the effects of other medicines. Talk to your nuclear medicine doctor if you are taking other medicines. If you are breast-feeding, talk to your nuclear medicine doctor before administration of this medicine. If you are addicted to alcohol, talk to your nuclear medicine doctor before administration of this medicine.

3. How Sogacin is used

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Sogacin will only be used in special controlled areas. This product will only be handled and given to you by people who are trained and qualified to use it safely. These persons will take special care for the safe use of this product and will keep you informed of their actions.

The nuclear medicine doctor supervising the procedure will decide on the quantity of Sogacin to be used in your case. It will be the smallest quantity necessary to get the desired information.
The quantity to be administered usually recommended for an adult ranges from 100 to 200 MBq (depending on the patient's body weight, the type of camera used for imaging and the acquisition mode). Megabecquerel (MBq) is the unit used to express radioactivity.

Use in children and adolescents
In children and adolescents, the quantity to be administered will be adapted to the child's or adolescent's weight.

Administration of Sogacin and conduct of the procedure
Sogacin is administered intravenously.
One injection is sufficient to conduct the test that your nuclear medicine doctor needs.
After injection you will be offered a drink and asked to urinate immediately preceding the test.

Duration of the procedure
Your nuclear medicine doctor will inform you about the usual duration of the procedure.

After administration of Sogacin, you should
- avoid any close contact with young children and pregnant women for the 8 hours following the injection,
- urinate frequently in order to eliminate the product from your body.

The nuclear medicine doctor will inform you if you need to take any special precautions after receiving this medicine. Contact your nuclear medicine doctor if you have any questions.

If you have been given more Sogacin than you should
An overdose is unlikely because you will only receive a single dose of Sogacin precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the case of an overdose, you will receive the appropriate treatment.
The elimination of the radioactive constituents should be increased as much as possible. You should drink as much as possible and frequently empty your bladder. It may become necessary to take diuretics.

Should you have any further question on the use of Sogacin, please ask the nuclear medicine doctor who supervises the procedure.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The spleen is an organ located in the abdomen (belly). Some people are born with an extra spleen (an accessory spleen). Extra spleen tissue may also be found in the abdomen following surgery or trauma to the spleen (this is known as splenosis). Gallium (^{68}Ga) edotreotide may make an accessory spleen or splenosis visible during medical imaging. There have been reports where this has been mistaken for a tumour. Your doctor may therefore perform additional scans and tests to confirm the findings on Gallium (^{68}Ga) edotreotide imaging (see section 2).

No serious adverse effects have been observed to date.

This administered radiopharmaceutical will deliver low amounts of ionising radiation with the least risk of cancer and hereditary abnormalities.

Your nuclear medicine doctor has considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical overcomes the risk due to radiation.

Reporting of side effects
If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system (-). By reporting side effects you can help provide more information on the safety of this medicine.

5. How Sogacin is stored

You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in appropriate premises. Storage of radiopharmaceuticals will be in accordance with national regulation on radioactive materials.

The following information is intended for the specialist only.
Sogacin must not be used after the expiry date which is stated on the label.

6. Contents of the pack and other information

What Sogacin contains
- The active substance is: gallium (^{68}Ga) edotreotide. One mL contains 20 MBq of gallium (^{68}Ga) edotreotide at date and time of calibration.
- The other ingredients are: water for injections, sodium chloride and ethanol.

What Sogacin looks like and contents of the pack
Sogacin is a clear and colourless solution.
The total activity of the vial is 200 MBq at date and time of calibration.

Marketing Authorisation Holder

ITM Medical Isotopes GmbH
Lichtenbergstr. 1
85748 Garching/Munich
Germany

Manufacturer

Alliance Medical RP GmbH
Spessartstraße 9
53119 Bonn
Germany

(For France and Austria)
Curium Austria GmbH
Seilerstätte 4
4020 Linz
Austria

(For Germany only)
ITM Medical Isotopes GmbH
Lichtenbergstr. 1
85748 Garching/Munich
Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

France	SOGACIN 20 MBq/mL, solution injectable
Austria	Sogacin 20 MBq/ml, Injektionslösung
Germany	TOCscan 20 MBq/ml Injektionslösung

This leaflet was last revised in {Month} {Year}.

Other sources of information
Detailed information on this medicine is available on the web site of {member state medicines agency}: http://www.{ }.

The following information is intended for healthcare professionals only:
The complete SmPC of Sogacin is provided as a separate document in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical.
Please refer to the SmPC.