Package leaflet: Information for the user

SomaKit TOC® 40 micrograms kit for radiopharmaceutical preparation
edotreotide

Read all of this leaflet carefully before you are given 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 SomaKit TOC is and what it is used for

This medicine is a radiopharmaceutical for diagnostic use only. It contains the active substance edotreotide. Before it can be used, the powder in the vial is mixed with a radioactive substance called gallium (^{68}Ga) chloride to make gallium (^{68}Ga) edotreotide (this procedure is called radiolabelling).

Gallium (^{68}Ga) edotreotide contains a small amount of radioactivity. After injection into a vein, it can make parts of the body visible to doctors during a medical imaging procedure called positron emission tomography (PET). This medical procedure obtains images of your organs to help locate abnormal cells or tumours, giving valuable information about your disease.

The use of SomaKit TOC involves exposure to small amounts of radioactivity. Your doctor and the nuclear medicine doctor have considered that the clinical benefit from the procedure with the radiopharmaceutical outweighs the risk due to radiation.

2. What you need to know before SomaKit TOC is used

SomaKit TOC must not be used
- if you are allergic to edotreotide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your nuclear medicine doctor before you are given SomaKit TOC:
- if you experienced any signs of allergic reaction (listed in section 4) after previous administration of SomaKit TOC;
- if you have kidney or liver problems (renal or hepatic disease);
- if you are under 18 years of age;
- if you have signs of dehydration before and after the examination;
- if you have other 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 the 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 have been taking other medicines, such as somatostatin analogues and glucocorticoids, which may interact with SomaKit TOC;
- if you are pregnant or believe you may be pregnant;
- if you are breast-feeding.

Your nuclear medicine doctor will inform you if you need to take any other special precaution before or after using SomaKit TOC.

Before administration of SomaKit TOC
You should drink plenty of water before the start of the examination in order to urinate as often as possible during the first hours after the procedure to ensure that SomaKit TOC is removed as quickly as possible from your body.

Children and adolescents
This medicine is not recommended in patients under 18 years of age because its safety and efficacy have not been established in this patient population.

Other medicines and SomaKit TOC
Tell your nuclear medicine doctor if you are taking, have recently taken or might take any other medicines, including somatostatin analogues or glucocorticoids (also called corticosteroids), since they may interfere with the interpretation of the images. If you are taking somatostatin analogues you might be asked to stop your treatment for a short period of time.

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 SomaKit TOC 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.

There is no information about the safety and the efficacy of the use of this medicine during pregnancy. Only essential investigations should be carried out during pregnancy, when the likely benefit far exceeds any risk to the mother and foetus.

If you are breast-feeding the nuclear medicine doctor may either delay the medical procedure until you are no longer breast-feeding or ask you to stop breast-feeding and to discard your milk until there is no radioactivity in your body (12 hours after the administration of SomaKit TOC).
Please ask your nuclear medicine doctor when you can resume breast-feeding.

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

SomaKit TOC contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium free’.

3. How SomaKit TOC is used

There are strict laws on the use, handling and disposal of radiopharmaceutical products. SomaKit TOC will only be used in special controlled areas. This medicine 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 medicine and will keep you informed of their actions.

The nuclear medicine doctor supervising the procedure will decide on the quantity of SomaKit TOC 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 MBq to 200 MBq (megabecquerel, the unit used to express radioactivity).

Administration of SomaKit TOC and conduct of the procedure
After radiolabelling, SomaKit TOC is administered by intravenous injection.
A single injection is sufficient to conduct the test that your doctor needs.
After injection, you will be offered something to 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 SomaKit TOC, you should:
- avoid any close contact with young children and pregnant women for 12 hours after the injection
- urinate frequently in order to eliminate the medicine 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 SomaKit TOC than you should
An overdose is unlikely because you will only receive a single dose under controlled conditions by the nuclear medicine doctor supervising the procedure. However, in the case of an overdose, you will receive the appropriate treatment. Drinking and emptying your bladder frequently will help remove the radioactive substance from your body more quickly.

Should you have any further questions on the use of SomaKit TOC, 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.

Although no side effects have been reported, a potential risk of allergic reactions (hypersensitivity) exists with SomaKit TOC. Symptoms may include: warm flush, redness of the skin, swelling, itching, nausea and difficulty breathing. In the event of an allergic reaction you will receive the appropriate treatment from your medical staff.

<u>Not known (frequency cannot be estimated from the available data):</u>
- Stinging near the injection site

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).

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

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 Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How SomaKit TOC 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.

Keep this medicine out of the sight and reach of children.

SomaKit TOC must not be used after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C to 8°C).
Store in the original package in order to protect from light.

After radiolabelling, SomaKit TOC should be used within 4 hours. Do not store above 25°C after radiolabelling.

SomaKit TOC must not be used if there are visible signs of deterioration.

Do not throw away any medicines via wastewater or household waste. Wait for the level of radioactivity to decay adequately before throwing away radioactive products. These measures will help protect the environment.

6. Contents of the pack and other information

What SomaKit TOC contains
- The active substance is edotreotide. Each vial of powder for solution for injection contains 40 micrograms of edotreotide.
- The other ingredients are: 1,10-phenanthroline, gentisic acid, mannitol, formic acid, sodium hydroxide, water for injections.

After radiolabelling, the solution obtained also contains hydrochloric acid.

What SomaKit TOC looks like and contents of the pack
SomaKit TOC is a kit for radiopharmaceutical preparation containing:
- A glass vial with black flip-off cap containing a white powder.
- A cyclic olefin polymer vial with yellow flip-off cap containing a clear and colourless solution.

The radioactive substance is not part of the kit and should be added during the preparation steps before injection.

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The following information is intended for healthcare professionals only:

The complete SmPC of SomaKit TOC is provided as a separate document in the medicinal 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.