Package leaflet: Information for the patient

Tekcis 2-50 GBq radionuclide generator
sodium pertechnetate (^{99m}Tc)

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 Tekcis is and what it is used for

This medicine is a radiopharmaceutical product for diagnostic use only.

Tekcis is a technetium (^{99m}Tc) generator, which means it is a device used to obtain a solution for injection of sodium pertechnetate (^{99m}Tc).

When this radioactive solution is injected, it temporarily collects in certain areas of the body. The low quantity of radioactivity injected can be detected outside of the body by special cameras. The nuclear medicine doctor will then take an image (scan) of the concerned organ which can give him valuable information about the structure and the function of this organ.

After injection the sodium pertechnetate (^{99m}Tc) solution is used to obtain images of various body parts such as the:
- thyroid gland
- salivary glands
- appearance of stomach tissue in an abnormal location (Meckel's Diverticulum)
- tear ducts of the eyes

The sodium pertechnetate (^{99m}Tc) solution can also be used in combination with another product to prepare another radiopharmaceutical medicine. In this case, please refer to the corresponding package leaflet.

The nuclear medicine doctor will explain to you what type of examination will be performed with this product.
The use of sodium pertechnetate (^{99m}Tc) solution does involve exposure to small amounts of radioactivity. Your doctor and the nuclear medicine doctor have 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 sodium pertechnetate (^{99m}Tc) solution obtained with Tekcis is used

The sodium pertechnetate (^{99m}Tc) solution obtained with Tekcis must not be used:
- if you are **allergic** to sodium pertechnetate (^{99m}Tc) or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Inform your nuclear medicine doctor in the following cases:
- if you suffer from **allergies**, as a few cases of allergic reactions have been observed after administration of sodium pertechnetate (^{99m}Tc) solution,
- if you suffer from kidney disease
- 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 special precautions after using this medicine. Talk to your nuclear medicine doctor if you have any questions.

Before administration of sodium pertechnetate (^{99m}Tc) solution 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 study.
- you should be fasting for 3 to 4 hours before Meckel's diverticulum scintigraphy to keep the small bowel peristalsis low.

Children and adolescents
Please talk to your nuclear medicine doctor if you or your child are under 18 years old.

Other medicines and sodium pertechnetate (^{99m}Tc) solution
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, and especially the following medicines:
- **atropine**, used for example:
  - to reduce stomach, bowel or gall bladder spasms
  - to reduce pancreas secretions
  - in ophthalmology
  - before administering an anaesthesia
  - to treat reduced heart beat or
  - as an antidote
- **isoprenaline**, a medicine to treat reduced heart beat
- **pain killers**
- **laxatives** (they should not be taken during this procedure since they irritate the gastrointestinal tract)
- if you had **contrast-enhanced studies** (e.g. with the contrast agent barium) **or upper gastro-intestinal examination** (as these should be avoided within 48h prior to Meckel's diverticulum scintigraphy)

- **antithyroid medicines** (e.g. carbimazole or other imidazole derivatives such as propylthiouracil, **salicylates, steroids, sodium nitroprusside, sodium sulfobromophtalein, perchlorate**) (as they should not be taken for 1 week prior to scintigraphy)
- **phenylbutazone** to treat fever, pain and inflammation in the body (as it should not be taken for 2 weeks prior to scintigraphy)
- **expectorants** (as they should not be taken for 2 weeks prior to scintigraphy)
- **natural or synthetic thyroid preparations** (e.g. sodium thyroxine, sodium liothyronine, thyroid extract) (as they should not be taken for 2-3 weeks prior to scintigraphy)
- **amiodarone** an antiarrhythmic agent (as it should not be taken for 4 weeks prior to scintigraphy)
- **benzodiazepines** used for example for sedation, or as anti-anxiety or anti-convulsion or muscle relaxant medication or **lithium** used as a mood stabiliser in manic-depressive illness (as both should not be taken for 4 weeks prior to scintigraphy)
- **iodide contrast agents** for radiologic examinations of the body (as they should not have been administered for 1-2 months prior to scintigraphy)

Please ask your nuclear medicine specialist before taking any medicines.

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 sodium pertechnetate (^{99m}Tc) solution 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, your nuclear medicine doctor will only administer this medicine during pregnancy if a benefit is expected which would far outweigh the risks.

If you are breast-feeding, please tell your nuclear medicine doctor, as he/she will advise you to stop doing so until the radioactivity has left your body. This takes about 12 hours. The expressed milk should be discarded. Resuming breast-feeding should be in agreement with the specialist in Nuclear Medicine who will supervise the procedure.

Driving and using machines
Sodium pertechnetate (^{99m}Tc) solution has no influence on the ability to drive and use machines.

Sodium pertechnetate solution contains sodium
Sodium pertechnetate solution contains 3.6 mg/mL of sodium. Depending on the volume injected, the limit of 1 mmol (23 mg) of sodium per dose administered may be exceeded. This must be taken into account if you are on a low-salt diet.

3. How the sodium pertechnetate (^{99m}Tc) solution obtained with Tekcis is used

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Tekcis 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 sodium pertechnetate (^{99m}Tc) solution to be used in your case. It will be the smallest quantity necessary to get the desired information. The quantity usually recommended to be administered for an adult ranges depending on the test to be performed, and ranges between 2 and 400 MBq (megabecquerel, 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 weight.

Administration of sodium pertechnetate (^{99m}Tc) solution and conduct of the procedure
Depending on the purpose of the examination, the product will be administered by injection into an arm vein or may be instilled into the eyes in the form of drops.
One administration is sufficient to conduct the test that your doctor needs.

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

Scans can be performed at any time, between the time of injection and for up to 24 hours after the administration, depending on the type of examination.

After administration of sodium pertechnetate (^{99m}Tc) solution has been performed you should:
- avoid any close contact with young children and pregnant women for the 12 hours following the injection
- urinate frequently in order to eliminate the product from your body
- after administration, you will be offered a drink and asked to urinate immediately preceding the test.

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 sodium pertechnetate (^{99m}Tc) solution obtained with Tekcis than you should:
An overdose is almost impossible, because you will only receive a single dose of sodium pertechnetate (^{99m}Tc) solution precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the case of an overdose, you will receive the appropriate treatment. In particular, the nuclear medicine doctor in charge of the procedure may recommend that you drink plenty of fluids to remove the traces of radioactivity from your body.

Should you have any further questions on the use of this product, please ask your 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.

Side effect with frequency not known (cannot be estimated from the available data):
- **allergic reactions, with symptoms such as**
- skin rash, itching
- hives
- swelling at various locations, e.g. of the face
- shortage of breath
- redness of the skin
- coma
- **circulatory reactions, with symptoms such as**
- rapid heart beat, slow heart beat
- fainting
- blurred vision
- dizziness
- headache
- flushing
- **gastrointestinal disorders, with symptoms such as**
- being sick (vomiting)
- feeling sick (nausea)
- diarrhoea
- **injection site reactions, with symptoms such as**
- skin inflammation
- pain
- swelling
- redness

This radiopharmaceutical product 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 doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:
HPRA Pharmacovigilance
Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tekcis

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.

6. Contents of the pack and other information

What Tekcis contains

- The active substance is: sodium pertechnetate (^{99m}Tc) solution.

- The other ingredients are: sodium chloride, sodium nitrate and water for injection.

What Tekcis looks like and contents of the pack

The product is sodium pertechnetate (^{99m}Tc) solution provided by a radionuclide generator.

Tekcis has to be eluted and the obtained solution may be used itself or to radiolabel some particular kits for radiopharmaceutical preparation.

Pack size:

^{99m}Tc activity **(Maximal eluable activity at calibration date, 12h CET)**	**2**	**4**	**6**	**8**	**10**	**12**	**16**	**20**	**25**	**50**	**GBq**
^{99}Mo activity **(at calibration date, 12h CET)**	**2.5**	**5**	**7**	**9.5**	**12**	**14.5**	**19**	**24**	**30**	**60**	**GBq**

Marketing Authorisation Holder and Manufacturer

CIS bio international
B.P. 32
F-91192 Gif-sur-Yvette Cedex

Manufacturer

CIS bio international
B.P. 32
F-91192 Gif-sur-Yvette Cedex

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names::
Austria, Belgium, Bulgaria, Cyprus, Croatia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom (Northern Ireland): Tekcis
Czech Republic: Technecistan-(^{99m}Tc) sodný CIS bio international

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Other sources of information

Detailed information on this medicine is available on the website of the Health Products Regulatory Authority (HPRA) (www.hpra.ie).

The following information is intended for healthcare professionals only:

The complete SmPC of Tekcis 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 (SmPc should be included in the box).