

Summary Public Assessment Report

Poltechnet (sodium molybdate [99Mo] / sodium pertechnetate [99mTc])

SE/H/1365/01/DC

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Poltechnet

(sodium molybdate [^{99}Mo] / sodium pertechnetate [$^{99\text{m}}\text{Tc}$])

9.1– 200 GBq[^{99}Mo] / 8.0- 175 GBq[$^{99\text{m}}\text{Tc}$], radionuclide generator

This is a summary of the public assessment report (PAR) for Poltechnet. It explains how Poltechnet was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Poltechnet.

For practical information about using Poltechnet, patients should read the package leaflet or contact their doctor or pharmacist.

What is Poltechnet and what is it used for?

Poltechnet is a ‘generic medicine’. This means that Poltechnet is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Drytec.

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

This medicine is a radiopharmaceutical product for diagnostic use only.

After injection the sodium pertechnetate ($^{99\text{m}}\text{Tc}$) 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 diverticulum)
- tear ducts of the eyes

The sodium pertechnetate ($^{99\text{m}}\text{Tc}$) 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.

How does Poltechnet work?

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.

How is Poltechnet used?

The pharmaceutical form of Poltechnet is radionuclide generator for intravenous injection. 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.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Poltechnet have been shown in studies?

No additional studies were needed as Poltechnet is a generic medicine that is given by intravenous injection and contains the same active substance as the reference medicine, Drytec.

What are the possible side effects of Poltechnet?

Because Poltechnet is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Poltechnet approved?

It was concluded that, in accordance with EU requirements, Poltechnet has been shown to have comparable quality and to be similar to the reference medicine Drytec. Therefore, the Medical Products Agency in Sweden decided that, as for Drytec, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Poltechnet?

A risk management plan has been developed to ensure that Poltechnet is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Poltechnet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Poltechnet

The marketing authorisation for Poltechnet was granted on 2015-06-11 in Sweden.

The full PAR for Poltechnet can be found on the following website:

<http://mri.medagencies.org/Human/>. For more information about treatment with Poltechnet, please read the [package leaflet](#) or contact your doctor or pharmacist.

This summary was last updated in 2015-06.