swissmedic

Summary report on authorisation dated 29 May 2026

RoTecPSMA® (active substance: trofolastat)

Authorisation in Switzerland: 8 August 2025

Diagnostic kit for use after radiolabelling to determine whether planned PSMA-targeted therapy is suitable for adult patients with metastatic prostate cancer.

About the medicinal product

RoTecPSMA is a diagnostic radiopharmaceutical[1] containing the active substance trofolastat. After labelling with radioactive sodium pertechnetate (99mTc), the resulting technetium (99mTc) trofolastat is used for an imaging examination.

Prostate cancer is the third commonest cause of death by cancer in Europe. In advanced stages, it can spread beyond the prostate to other areas of the body, such as the lymph nodes or bones. It is then known as metastatic prostate cancer.

Various treatment options are available for patients with metastatic prostate cancer, including PSMA-targeted therapies. However, these treatments can only be used if the cancer cells exhibit sufficient prostate-specific membrane antigen (PSMA). For this reason, it is necessary to determine whether patients have any PSMA-positive lesions before they start treatment of this kind.

Radiolabelled RoTecPSMA (trofolastat) can be used to detect PSMA-positive lesions by SPECT/CT so that a decision can be made on whether PSMA-targeted therapy is suitable for the patient.

SPECT/CT is a nuclear medicine three-dimensional imaging technique. SPECT is used in most European countries and is considered cost-effective.

Mode of action

PSMA is a protein that occurs in large amounts on the surface of most prostate cancer cells.
After radiolabelling with technetium (99mTc), the active substance trofolastat binds specifically to PSMA and thus to prostate cancer cells. SPECT imaging makes the radiolabelled cancer cells visible so that the areas of the body affected by prostate cancer can be identified.

[1] Diagnostic radiopharmaceutical: A radioactive substance that is introduced into the body to make certain tissues or diseases visible by means of imaging techniques.

Administration

RoTecPSMA is a prescription-only medicine that is supplied as a kit for preparation of a solution for injection into the veins.

The diagnostic agent contains the active substance trofolastat, which has to be radiolabelled prior to use. The recommended radioactivity for adults is 740+/- 111 MBq.

The medicinal product may only be used by appropriately trained healthcare professionals with experience of nuclear medicine diagnostics and is intended solely for use in institutions that hold a permit to use radioactive substances.

Efficacy

Retrospective analyses showed that RoTecPSMA is suitable for detecting PSMA-positive cancer cells in patients who are already known to have metastatic prostate cancer and thus facilitates the selection of patients for PSMA-targeted therapy.

Precautions, undesirable effects, & risks

RoTecPSMA must not be used in those who are hypersensitive to the active substance or any of the excipients.

RoTecPSMA should only be used by qualified specialists.

It contributes to patients' total long-term cumulative radiation exposure. This is associated with an increased risk of cancer and genetic defects.

The commonest reported adverse reactions (affecting 1% or more of patients) were headache, dizziness, fatigue and nausea.

No serious adverse events or deaths have been reported in connection with radiolabelled RoTecPSMA.

All precautions, risks, and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

Various imaging techniques are used to diagnose prostate cancer.

Radiolabelled RoTecPSMA offers a new way of specifically identifying tumours. The risks associated with the radioactive marker primarily involve increased radiation exposure. However, these can be minimised by appropriate handling.

Taking all the risks and precautions into account, and based on the available data, the benefits of RoTecPSMA outweigh the risks. Swissmedic has therefore authorised RoTecPSMA containing the active substance trofolastat in Switzerland for the identification of PSMA-positive lesions in patients with metastatic prostate cancer for whom PSMA-targeted therapy is planned.

Further information on the medicinal product

At the time of publication of the Summary report on authorisation for RoTecPSMA, the Information for healthcare professionals was not yet available. As soon as the medicinal product becomes available in Switzerland, the Information for healthcare professionals will be made available on the following website: www.swissmedicinfo-pro.ch. Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.