swissmedic

Summary report on authorisation dated 21 November 2025

Radelumin® (active substance: [^{18}F]PSMA-1007)

Authorisation in Switzerland: 11 June 2024

Solution for injection for the detection by imaging of PSMA-positive lesions in adults with prostate cancer

About the medicinal product

Radelumin is a diagnostic radiopharmaceutical[1] containing the active substance [^{18}F]PSMA-1007. It is administered as a solution for injection.

Radelumin contains the radioactive isotope fluorine-18. This can be used to identify PSMA-positive lesions[2] in adults with prostate cancer with the aid of positron emission tomography (PET)[3].

Prostate cancer is the second most frequent type of cancer in men: in 2022, there were 1.47 million diagnoses worldwide. (Source: GCO, WHO)

Mode of action

PSMA is a protein that occurs in large amounts on the surface of most prostate cancer cells. The active substance [^{18}F]PSMA-1007, which contains radioactive fluorine-18, binds to PSMA and thus to prostate cancer cells. By combining PET with computed tomography (PET-CT), the radioactively marked cancer cells can be visualised so that the areas within the body that are affected by prostate cancer can be identified.

Administration

Radelumin is a prescription-only medicine that is supplied as a solution for injection into the veins. The medicinal product contains the active substance [^{18}F]PSMA-1007, the radioactivity of which is 200–4500

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

[2] PSMA-positive lesions: Pathological changes in tissue that exhibit prostate-specific membrane antigen (PSMA).

[3] PET: Positron emission tomography (PET) is a body scan used to show metabolic activity in the tissue.

MBq[4]/mL, and is intended solely for administration in institutions that hold a permit to use radioactive substances.

The recommended dose is 2–4 MBq/kg body weight up to a maximum dose of 360 MBq.

Radelumin is administered by appropriately qualified professional medical staff.

Efficacy

The efficacy of Radelumin was investigated in a randomised study[5] entitled ABX-CT-301. This study compared Radelumin with [^{18}F]-fluorocholine in patients whose prostate cancer had recurred after first treatment. The key data on efficacy were obtained in 190 participants who had each undergone PET-CT with both study medications. The primary goal of the study was to demonstrate the superiority of Radelumin over [^{18}F]-fluorocholine in terms of tumour detection rate. The PET-CT images were evaluated by independent assessors. The study showed that tumours were detected in 77% of cases with Radelumin compared with 57% of cases with [^{18}F]-fluorocholine.

Precautions, undesirable effects, & risks

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

Radelumin 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.

No undesirable effects associated with Radelumin in clinical use have been reported to date.

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. The diagnostic radiopharmaceutical Radelumin offers a new option for the targeted identification of tumours. Clinical studies have shown that a better tumour detection rate can be achieved with Radelumin than with [^{18}F]-fluorocholine, the product that is currently authorised. 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 Radelumin outweigh the risks. Swissmedic has therefore authorised the medicinal product Radelumin, containing the active substance [^{18}F]PSMA-1007, for use in Switzerland.

[4] MBq: A mega-Becquerel is the unit of activity of a determined quantity of a radioactive substance. M stands for "mega", i.e. one million

[5] Randomised study: Tests different treatments by assigning participants to different groups at random.

Further information on the medicinal product

At the time of publication of the Summary report on authorisation for Radelumin, 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.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.