swissmedic

Summary report on authorisation dated 21 November 2025

Lutathera® (active substance: lutetium (^{177}Lu) oxodotreotide)

First authorisation in Switzerland: 22 November 2024

Solution for infusion for the treatment of metastatic or unresectable, progressive, well-differentiated (G1 and G2) somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs) in adults

About the medicinal product

Lutathera contains the active substance lutetium (^{177}Lu) oxodotreotide and is a therapeutic radiopharmaceutical[1] consisting of the radioactive isotope lutetium-177 and non-radioactive oxodotreotide.

Lutathera is used in adults to treat certain tumours in the gastrointestinal tract or pancreas.

These tumours are called "Gastroenteropancreatic neuroendocrine tumours (GEP-NETs)".

Treatment with Lutathera can be considered if

- The cancer cannot be completely removed by surgery (unresectable);
- The cancer spreads to other parts of the body (metastases); or
- The disease continues to progress despite other treatments (progressive)

In addition, the tumour must be well-differentiated (meaning the tumour cells still bear a relatively strong resemblance to normal cells and are generally slower-growing – what are termed Grade G1 or G2) and must have somatostatin receptors (docking points to which the medicinal product can attach) on its surface.

Oxodotreotide, the non-radioactive component of the active substance, binds to the receptors mentioned above so that lutetium-177, the radioactive component, can attack the cancer cell.

In deciding whether to authorise Lutathera, Swissmedic took into account the assessment of the clinical data for Lutathera CA, a medicinal product that is already authorised.

Accordingly, the requirements for issuing a comprehensive SwissPAR (Swiss Public As-

[1] Therapeutic radiopharmaceutical A therapeutic radiopharmaceutical is a radiolabelled medicinal product used to treat cancer. It binds specifically to certain cancer cells and emits radiation to kill the cells.

sessment Report – a detailed report for professionals) and a Summary report on authorisation based on this SwissPAR have not been fulfilled.

The difference between Lutathera and Lutathera CA:

Lutathera and Lutathera CA both contain the active substance lutetium (^{177}Lu) oxodotreotide. Lutathera CA contains ^{177}lutetium. This contains the impurity lutetium^{177m}, which can be attributed to its manufacture from lutetium^{176}. This ^{177}lutetium is designated "carrier added" (CA). Lutathera contains ^{177}lutetium without the impurity ^{177m}lutetium, produced using ^{176}ytterbium. This is referred to as "non-carrier added" lutetium.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Lutathera®

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.