13 October 2016
EMA/603784/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

SomaKit TOC

edotreotide

On 13 October 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product SomaKit TOC, intended for use in Positron Emission Tomography (PET) imaging in adult patients with gastro-enteropancreatic neuroendocrine tumours (GEP-NET). SomaKit TOC was designated as an orphan medicinal product on 19 March 2015. The applicant for this medicinal product is Advanced Accelerator Applications.

SomaKit TOC will be available as a 40 micrograms kit for radiopharmaceutical preparation. The active substance of SomaKit TOC is edotreotide. Edotreotide is for radiolabelling with gallium (^{68}Ga) chloride solution and binds with high affinity to somatostatin receptors (SSTRs) in tumours that overexpress SSTRs (ATC code: V09IX09).

The benefits with SomaKit TOC are its ability to detect tumours that overexpress SSTRs in patients with GEP-NETs with high sensitivity and specificity. No adverse reactions related to gallium (^{68}Ga) edotreotide have been reported; however, exposure to ionising radiation is a potential risk, as for other radiopharmaceuticals.

The full indication is:

"This medicinal product is for diagnostic use only. After radiolabelling with gallium (^{68}Ga) chloride solution, the solution of gallium (^{68}Ga) edotreotide obtained is indicated for Positron Emission Tomography (PET) imaging of somatostatin receptor overexpression in adult patients with confirmed or suspected well-differentiated gastro-enteropancreatic neuroendocrine tumours (GEP-NET) for localizing primary tumours and their metastases". It is proposed that SomaKit TOC be administrated by trained healthcare professionals with technical expertise in using and handling nuclear medicine diagnostic agents and only in a designated nuclear medicine facility.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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