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EPAR summary for the public

SomaKit TOC

edotreotide

This is a summary of the European public assessment report (EPAR) for SomaKit TOC. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use SomaKit TOC.

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

What is SomaKit TOC and what is it used for?

SomaKit TOC is a diagnostic medicine used in adult patients who are thought to have so-called well-differentiated gastroenteropancreatic neuroendocrine tumours (GEP-NETs). GEP-NETs are cancers which start in types of cells in the gut or pancreas that normally release hormones. The tumours can then spread elsewhere in the body (metastasis).

SomaKit TOC is used with a technique called positron emission tomography (PET scan) to obtain images that locate the cancers. SomaKit TOC contains the active substance edotreotide. The medicine is not used directly, but must be 'radiolabelled' before being injected, which means that it is tagged with a separate substance that emits small amounts of radiation. The substance that is used for radiolabelling SomaKit TOC is called gallium (^{68}Ga) chloride.

Because the number of patients with GEP-NETs is low, the disease is considered 'rare', and SomaKit TOC was designated an 'orphan medicine' (a medicine used in rare diseases) on 19 March 2015.

How is SomaKit TOC used?

SomaKit TOC is available as a kit for preparing a solution for injection. It is given as a single injection into a vein immediately after being radiolabelled. The PET scan images are then taken 40 to 90 minutes later.

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SomaKit TOC can only be obtained with a prescription and the injection must only be prepared and given in a suitable facility by experts in handling radioactive medicines.

For further information, see the package leaflet.

How does SomaKit TOC work?

The active substance in SomaKit TOC, edotreotide, attaches specifically to receptors called somatostatin receptors on the surface of cells. Not all cells have these receptors but most well-differentiated GEP-NET cells have high amounts on their surface. The prepared medicine, radiolabelled with gallium (^{68}Ga) chloride, attaches to these receptors on the GEP-NET cells. The resulting build-up of radiation can be detected by the special camera of the PET scan. This makes it possible to see where the tumours are and whether they have spread.

What benefits of SomaKit TOC have been shown in studies?

The active substance in SomaKit TOC, edotreotide radiolabelled with gallium (^{68}Ga) chloride, has a well established use in detecting GEP-NETs. The company therefore provided information from many, mostly small, studies in the published literature to show the effectiveness of SomaKit TOC at detection. The studies included data from 970 patients. Some studies looked at the sensitivity of the PET scans (how well the scans identified patients who had GEP-NETs or their metastases), some analysed specificity (how reliable scans were at identifying subjects who had no GEP-NETs) and some looked at lesion detection rate (how good scans were at identifying the tumours). A comparison using data from several of these studies (a meta-analysis) was also presented.

Taken together, the studies were sufficient to show the effectiveness of SomaKit TOC for detection, although the exact results varied. For localising the primary GEP-NET, one study showed that the medicine had a sensitivity of 45% compared with 10% in patients given another approved diagnostic medicine, indium (^{111}In) pentetreotide, and this was confirmed by another study that showed that the former had better sensitivity. Results of further studies indicated that edotreotide labelled with gallium (^{68}Ga) chloride had a sensitivity and specificity of 100% and 89% respectively, and found a lesion detection rate of 75%.

In four other comparative studies it was seen that the active substance in SomaKit TOC detected more tumours than did indium (^{111}In) pentetreotide in the same patients.

What are the risks associated with SomaKit TOC?

After SomaKit TOC is radiolabelled it emits a small amount of radiation which poses a low risk of cancer or hereditary abnormalities.

For the full list of side effects or restrictions with SomaKit TOC, see the package leaflet.

Why is SomaKit TOC approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) considered that the technical and diagnostic performance of the medicine had been demonstrated. The risks of side effects seemed to be low and the CHMP therefore decided that SomaKit TOC's benefits are greater than its risks and recommended that it be approved for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of SomaKit TOC have been included in the summary of product characteristics and the package leaflet.

Other information about SomaKit TOC

The European Commission granted a marketing authorisation valid throughout the European Union for SomaKit TOC on 08 December 2016.

The full EPAR for SomaKit TOC can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with SomaKit TOC, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for SomaKit TOC can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designation.

This summary was last updated in 12-2016.