EMA/471814/2023
EMEA/H/C/005626

Elucirem (*gadopiclenol*)

An overview of Elucirem and why it is authorised in the EU

What is Elucirem and what is it used for?

Elucirem is a 'contrast agent', a medicine used to improve the contrast of images obtained during magnetic resonance imaging (MRI) examinations. This helps doctors find certain pathologies in patients in whom this would not be possible otherwise. Elucirem is used in adults and children from 2 years of age.

Elucirem contains the active substance gadopiclenol.

How is Elucirem used?

Elucirem is given as an injection into a vein by a specialised healthcare professional, just before the MRI scan. It can only be obtained with a prescription.

For more information about using Elucirem, see the package leaflet or contact your doctor or pharmacist.

How does Elucirem work?

The active substance in Elucirem, gadopiclenol, contains gadolinium, a 'rare-earth' metal element used in contrast agents to help obtain better MRI images. MRI is an imaging method that relies on the tiny magnetic fields produced by water molecules in the body. Once injected, gadolinium interacts with the water molecules. As a result of this interaction, the water molecules give a stronger signal in the locations reached by the contrast agent, and this helps to obtain a brighter picture.

What benefits of Elucirem have been shown in studies?

Two main studies were carried out to investigate whether MRI images made with Elucirem were comparable to those made with another contrast agent, and better than those made without a contrast agent. One study involved 256 adults who had, or were highly suspected to have, a tumour in their brain or spinal cord, based on the outcome of a previous imaging procedure (such as an MRI or CT scan). The second study involved 304 adults with a tumour or other pathological tissue (such as a cyst) in another part of their body.

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Study participants had MRI scans in combination with Elucirem, in combination with another gadolinium-based contrast agent and without a contrast agent. Doctors experienced in analysing MRI images then compared how clearly the tumours or pathologies were visible in the different scans. All doctors considered that MRI images with Elucirem were clearer than those made without a contrast agent, and comparable with those made with the other contrast agent.

What are the risks associated with Elucirem?

For the full list of side effects and restrictions with Elucirem, see the package leaflet.

The most common side effects with Elucirem (which may affect up to 1 in 10 people) include headache and injection site reactions. Other common side effects (which may affect up to 1 in 100 people) include nausea, fatigue and diarrhoea.

Why is Elucirem authorised in the EU?

Using Elucirem as a contrast agent improved the quality of the resulting MRI scan compared to an unenhanced scan. The safety profile of Elucirem is in line with that of other gadolinium-based contrast agents. Importantly, Elucirem contains gadolinium in a specific complex. This means that it can be given at half the dose of gadolinium compared with other, non-specific gadolinium-containing contrast agents while providing the same contrast enhancement. The European Medicines Agency therefore decided that Elucirem's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

As for all medicines, data on the use of Elucirem are continuously monitored. Suspected side effects reported with Elucirem are carefully evaluated and any necessary action taken to protect patients.

Other information about Elucirem

Elucirem received a marketing authorisation valid throughout the EU on 07 December 2023.

Further information on Elucirem can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/elucirem.

This overview was last updated in 12-2023.