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Elucirem® (active substance: gadopiclenol)

First authorisation in Switzerland: 21 December 2023

Contrast agent used in magnetic resonance imaging (MRI) in adults to visualise lesions with abnormal vascularity.

About the medicinal product

Elucirem contains the active ingredient gadopiclenol.

Gadopiclenol is a contrast agent used in magnetic resonance imaging (MRI; a type of imaging technique) in adults to help identify and visualise certain body structures. It is used in the examination of lesions[1] with abnormal vascularity (vascular density) in the central nervous system and other parts of the body.

Elucirem is used only when the diagnostic information is significant and cannot be obtained with an MRI without contrast enhancement.

Mode of action

Elucirem affects the water molecules, or protons, in the body. The magnetic field generated by an MRI scanner causes certain protons in the body's cells to be 'deflected' from their normal position. When the magnetic field is turned off, the protons return to their original position. This process produces a signal that the scanner processes into an image. Elucirem makes it possible to enhance this process because gadopiclenol has a stronger magnetic effect than the natural protons in the body. This means that the signal captured by the scanner is stronger, resulting in clearer and sharper images.

[1] Lesion: A lesion is damage to tissue caused by injury or disease.

Administration

Elucirem, containing the active substance gadopiclenol, is a prescription-only medicine.

It is used in the form of a solution for intravenous injection (into the veins).

The recommended dose is 0.05 mmol/kg body weight, which corresponds to 0.1 mL/kg body weight.

Patients are monitored for at least half an hour after administration so that any side effects can be identified and treated immediately.

Efficacy

The efficacy and safety of Elucirem were investigated in 2 studies.

The first study (GDX-44-010) focused on patients with contrast-enhanced lesions in the central nervous system, while the second study (GDX-44-011) focused on patients with contrast-enhanced lesions in other parts of the body. Patients with severe renal impairment and severe cardiac insufficiency were excluded from both studies.

In addition to an MRI scan without a contrast agent, the patients then received a further MRI scan with the first contrast agent during the same session. Following an interval of 2-14 days, the same patients underwent a second MRI session with and without the second contrast agent. Allocation to the first or second contrast agent was ensured by means of a randomisation procedure. Elucirem was compared with gadobutrol (an authorised contrast agent). The investigators and patients did not know which contrast agent was administered first (double blinding) and the images were analysed anonymously by 'blinded' experts, thus eliminating any influence on the test results.

In combination with the non-contrast-enhanced MRI images, Elucirem showed a significant superiority in the visualisation of lesions, which was confirmed by 3 defined categories: lesion delineation, internal morphology (internal composition and structure of contrast-enhancing lesions), and increase in contrast enhancement. Both Elucirem and gadobutrol showed similar increases in this information compared to the non-contrast-enhanced images.

In a direct comparison of Elucirem with gadobutrol, the results showed that Elucirem at a dose of 0.05 mmol/kg body weight delivered comparable results to the gadobutrol dose of 0.1 mmol/kg (statistical evidence of non-inferiority).

Elucirem is an effective way to improve MRI diagnostics and also reduce the dose of gadolinium required. No data are available on gadolinium deposition in human tissue (e.g. brain).

Precautions, undesirable effects, & risks

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

The most common adverse reactions associated with Elucirem are injection site reactions, headache, nausea, fatigue, and diarrhoea. In most patients, these reactions are mild and soon pass of their own accord.

The use of Elucirem is, however, associated with more serious risks and side effects. In the event of anaphylactic reactions (severe allergic shock) or severe cases of hypersensitivity, use should be stopped immediately and appropriate treatment initiated. Patients with severely impaired renal function are at increased risk of developing nephrogenic systemic fibrosis (NSF). Patients should be monitored for signs of renal impairment and Elucirem should be discontinued immediately if such impairment is suspected or confirmed.

All precautions, risks, and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

The studies demonstrated the benefit of Elucirem in improving MRI diagnostics. It demonstrated similar efficacy to authorised contrast agents, but with a reduced dose of gadolinium, which may reduce the risk of gadolinium deposition in tissues. However, there are no data on human tissue deposition with Elucirem.

Taking all the risks and precautions into account, and based on the available data, the benefits of Elucirem outweigh the risks. Swissmedic has therefore authorised the medicinal product Elucirem, containing the active substance gadopiclenol, for use in Switzerland.

Further information on the medicinal product

At the time of publication of the Public Summary SwissPAR for Elucirem, 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 Public Summary SwissPAR.

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