12 October 2023
EMA/CHMP/448539/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Elucirem

gadopiclenol

On 12 October 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Elucirem, intended for contrast-enhanced magnetic resonance imaging (MRI) to improve detection and, visualization of pathologies when diagnostic information is essential and not available with unenhanced MRI. The applicant for this medicinal product is Guerbet.

Elucirem will be available as a 0.5 mmol/ml solution for injection. The active substance of Elucirem is gadopiclenol, a paramagnetic contrast media (ATC code: V08CA12). Gadopiclenol is a macrocyclic non-ionic complex of gadolinium, the active moiety, which enhances the relaxation rates of water protons. This leads to an increase in MRI signal intensity (brightness) of tissues and enhances contrast.

The benefits of Elucirem is its potential to improve diagnostic information over unenhanced MRI in pathologies with disruption of the blood-brain barrier (BBB) and / or abnormal vascularity. The most common side effects are injection site pain, headache, nausea, injection site coldness, fatigue and diarrhoea. As with other gadolinium-containing contrast agents, hypersensitivity reactions, including life-threatening reactions, can occur.

The full indication is:

> This medicinal product is for diagnostic use only.
>
> Elucirem is indicated in adults and children aged 2 years and older for contrast-enhanced magnetic resonance imaging (MRI) to improve detection and, visualization of pathologies with disruption of the blood-brain-barrier (BBB) and/or abnormal vascularity of:
>
> - the brain, spine, and associated tissues of the central nervous system (CNS);
> - liver, kidney, pancreas, breast, lung, prostate, and musculoskeletal system.
>
> It should be used only when diagnostic information is essential and not available with

[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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unenhanced MRI.

Elucirem should only be administered by trained healthcare professionals with technical expertise in performing gadolinium enhanced MRI.

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 granted by the European Commission.