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Vueway (*gadopiclenol*)

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

What is Vueway and what is it used for?

Vueway 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. Vueway is used in adults and children from birth.

Vueway contains the active substance gadopiclenol.

How is Vueway used?

Vueway 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 Vueway, see the package leaflet or contact your doctor or pharmacist.

How does Vueway work?

The active substance in Vueway, 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 Vueway have been shown in studies?

Two main studies were carried out to investigate whether MRI images made with Vueway 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 Vueway, 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 Vueway were clearer than those made without a contrast agent, and comparable with those made with the other contrast agent.

Two additional studies were undertaken in children. The first involved 80 children aged from 2 to less than 18 years and the second involved 36 children aged less than 2 years. The studies did not compare gadopiclenol with another contrast agent. Each child first had MRI images taken without any contrast agent, followed by MRI images taken with gadopiclenol. The results showed that gadopiclenol made MRI images clearer and helped doctors make more confident diagnoses. Data also showed that Vueway behaves in a similar way in children as it does in adults.

What are the risks associated with Vueway?

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

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

Why is Vueway authorised in the EU?

Using Vueway as a contrast agent improved the quality of MRI scans compared to an unenhanced scans. The safety profile of Vueway is in line with that of other gadolinium-based contrast agents. Importantly, Vueway 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 Vueway'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 Vueway?

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

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

Other information about Vueway

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

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

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