Electronic Certificate

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Certification Statement
We certify that the final electronic form of this material is in accordance with the regulations set forth by the health authority for the country of this document, and is a fair and truthful presentation of the facts about the product.

Role	Signature
Marzia Michieletto - Regulatory Approval (marzia.michieletto@bracco.com)	Meaning: As the Regulatory, I approve this document for use. Date: 12-Feb-2026 07:58:32 GMT+0000

VUEWAY - ABBREVIATED SPC

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. Detailed information on this medicinal product is available on the website of the European Medicines Agency https://www.ema.europa.eu

1. NAME OF THE MEDICINAL PRODUCT

Vueway 0.5 mmol/mL solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 mL of solution contains 485.1 mg gadopiclenol (equivalent to 0.5 mmol of gadopiclenol and to 78.6 mg of gadolinium).

3. PHARMACEUTICAL FORM

Clear, colourless to pale yellow solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Diagnostic use only. Indicated in adults and children from birth for contrast-enhanced magnetic resonance imaging (MRI) for: the brain, spine, and associated tissues of the central nervous system (CNS); the liver, kidney, pancreas, breast, lung, prostate, and musculoskeletal system.
It should be used only when diagnostic information is essential and not available with unenhanced MRI.

4.2 Posology and method of administration

0.1 mL/kg body weight (BW) (equivalent to 0.05 mmol/kg BW) for all indications. For paediatric population from birth, more than one dose should not be used during a scan. Due to immature renal function in neonates up to 4 weeks of age and infants up to 1 year of age, Vueway should only be used in these patients after careful consideration, at a dose not exceeding 0.05 mmol/kg body weight. Because of the lack of information on repeated administration, Vueway injections should not be repeated unless the interval between injections is at least 7 days.
No adjustment needed for elderly, hepatic, or renal impairment. Caution in patients with severe renal impairment (GFR < 30 mL/min/1.73 m^2) and in patients in the perioperative liver transplantation period. Use only if essential and if non-contrast enhanced MRI not available. Interval between injections needs to be at least 7 days. Method of administration: intravenous use only,as a bolus injection. Since experience shows that most undesirable effects occur within minutes after administration, the patient should be kept under observation during and following administration for at least half an hour.

4.4 Special warnings and precautions for use

Gadopiclenol must not be used intrathecally. Serious, life-threatening and fatal cases, primarily with neurological reactions (e.g. coma, encephalopathy, seizures), have been reported with intrathecal use of gadolinium-based contrast agents.Usual precautions such as exclusion of patients with pacemakers, ferromagnetic vascular clips, infusion pumps, nerve stimulators, cochlear implants, or suspected intracorporal metallic foreign bodies, particularly in the eye. Potential for hypersensitivity or anaphylactic reactions: higher in patients with a history of previous reaction to gadolinium-containing contrast agents, bronchial asthma or allergy. Renal impairment and nephrogenic systemic fibrosis (NSF): patients undergoing liver transplantation are at particular risk. Elderly: As the renal clearance of gadopiclenol may be impaired in the elderly, it is particularly important to screen patients aged 65 years and older for renal dysfunction. Caution should be exercised in patients with renal impairment. Seizures: special caution in patients with a lowered threshold for seizures. Extravasation: In case of extravasation, the injection must be stopped immediately. Cardiovascular disease: in patients with severe cardiovascular disease, only after careful risk benefit assessment.

4.5 Interaction with other medicinal products and other forms of interaction
No interaction studies performed. Beta-blockers, vasoactive substances, angiotensin-converting enzyme inhibitors, angiotensin II receptor antagonists decrease the efficacy of the mechanisms of cardiovascular compensation for blood pressure disorders.

4.6 Fertility, pregnancy and lactation
Pregnancy: Vueway should not be used during pregnancy unless the clinical condition of the woman requires use of gadopiclenol.
Breast-feeding: Gadolinium-containing contrast agents are excreted into breast milk in very small amounts. Continuing or discontinuing breast feeding for a period of 24 hours after administration of Vueway, should be at the discretion of the doctor and breast-feeding mother.

4.8 Undesirable effects
The most frequent adverse reactions were injection site pain, headache, nausea, injection site coldness, fatigue and diarrhoea.
Hypersensitivity: Immediate reactions include one or more effects, which appear simultaneously or sequentially, which are most often cutaneous, respiratory and/or vascular reactions. Each sign may be a warning sign of a starting shock and go very rarely to death.
See full SmPC for details.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

4.9 Overdose
The maximum daily single dose tested in humans was 0.6 mL/kg BW (equivalent to 0.3 mmol/kg BW).
See full SmPC for details.

5.1 Pharmacodynamic properties
ATC code: V08CA12. Gadopiclenol is a paramagnetic agent for Magnetic Resonance Imaging (MRI).

6.3 Shelf life
3 years.

6.4 Special precautions for storage
For vials: any special storage conditions.
For pre-filled syringes: Do not freeze.

7. MARKETING AUTHORISATION HOLDER
Bracco Imaging SPA-Via Egidio Folli, 50. 20134 Milan, Italy.

8. MARKETING AUTHORISATION NUMBER(S)
EU/1/23/1773/001-025

10. DATE OF REVISION OF THE TEXT
January 22nd, 2026.