Vueway® (gadopiclenol) 0.5 mmol/mL, solution for injection – ABBREVIATED SmPC

▼Before use, refer to the full prescribing information.
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. See section 4.8 for how to report adverse reactions.

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). Full list of excipients (as in section 6.1 of full prescribing information): tetraxetan, trometamol , hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment), water for injections**.**

3. PHARMACEUTICAL FORM
Solution for injection. Clear, colourless to pale yellow solution

Mean osmolality at 37 °C	850 mOsm/kg H_2O
pH	7.0-7.8
Viscosity at 20 °C	12.5 mPa s
Viscosity at 37 °C	7.7 mPa s

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
This medicinal product is for diagnostic use only.
Vueway 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);
- 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
This medicinal product should only be administered by trained healthcare professionals with technical expertise in performing gadolinium enhanced MRI.
Posology
The recommended dose of Vueway is 0.1 mL/kg body weight (BW) (equivalent to 0.05 mmol/kg BW) to provide diagnostically adequate contrast for all indications. The dose should be calculated based on the patient's BW and should not exceed the recommended dose per kilogram of BW detailed in this section – see table 1 below.

BW (kg)	Volume (mL)	Quantity (mmols)
10	1	0.5
20	2	1.0
30	3	1.5
40	4	2.0
50	5	2.5
60	6	3.0
70	7	3.5
80	8	4.0
90	9	4.5
100	10	5.0
110	11	5.5
120	12	6.0
130	13	6.5
140	14	7.0

Table1: Volume of Vueway to be administered per BW

Elderly
No dose adjustment is necessary. Caution should be exercised in elderly patients (see section 4.4; for further details refer to section 5.2 of full prescribing information).
Renal impairment
No dose adjustment is necessary for patients with any level of renal impairment. Gadopiclenol should only be used in patients with severe renal impairment (GFR < 30 mL/min/1.73 m^2) and in patients in the perioperative liver transplantation period after careful risk/benefit assessment and if the diagnostic information is essential and not available with non-contrast enhanced MRI (see section 4.4). If it is necessary to use gadopiclenol, the dose should not exceed 0.1 mL/kg BW (equivalent to 0.05 mmol/kg BW). More than one dose should not be used during a scan. Because of the lack of information on repeated administration, gadopiclenol injections should not be repeated unless the interval between injections is at least 7 days.
Hepatic impairment
No dose adjustment is considered necessary for patients with hepatic impairment. Caution is recommended, especially in the case of perioperative liver transplantation period (see above "renal impairment").
Paediatric population (2 years and older)
The recommended and maximum dose of Vueway is 0.1 mL/kg BW (equivalent to 0.05 mmol/kg BW) for all indications. More than one dose should not be used during a scan. The safety and efficacy of Vueway in children less than 2 years has not yet been established. No data are available.
Method of administration
The medicinal product is for intravenous use only. The recommended dose is administered intravenously as a bolus injection at approximatively 2 mL/sec followed by a flush of sodium chloride 9 mg/ml (0.9%), solution for injection via manual injection or power injector. Intravenous administration of contrast agent should, if possible, be done with the patient lying down. 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 (see section 4.4). For instructions on the medicinal product before administration, see section 6.6 of full prescribing information.
Paediatric population
In children, Vueway in vials with a single use syringe of a volume adapted to the amount to be injected should be used in order to have better precision of the injected volume.
Image acquisition
Contrast-enhanced MRI can start after the injection depending on the pulse sequences used and the protocol for the examination. Optimal signal enhancement is generally observed during arterial phase and within a period of about 15 minutes after injection. Longitudinal relaxation times (T1)-weighted sequences are particularly suitable for contrast-enhanced examinations.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients (for details refer to section 2 above and section 6.1 of full prescribing information).

4.4 Special warnings and precautions for use

The usual precautions for MRI examination should be applied, 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.
MRI images produced with this medicinal product should only be analysed and interpreted by the healthcare professionals trained in interpretation of gadolinium enhanced MRI.
There are no or limited clinical data investigating the performance of gadopiclenol for CNS imaging in patients with inflammatory, infectious, autoimmune or demyelinating disorders (such as multiple sclerosis), patients with acute or chronic infarct, or patients with intramedullary spine lesions.
There are also no or limited clinical data investigating the performance of gadopiclenol for body imaging in patients with inflammatory, infectious and autoimmune conditions, including acute/chronic pancreatitis, inflammatory bowel disease, inflammatory diseases of head and neck region and endometriosis.
Potential for hypersensitivity or anaphylactic reactions

- As with other gadolinium-containing contrast agents, hypersensitivity reactions can occur, including life-threatening. Hypersensitivity reactions may be either allergic (described as anaphylactic reactions when serious) or non-allergic. They can occur either immediately (less than 60 minutes) after injection or delayed (up to 7 days). Anaphylactic reactions occur immediately and can be fatal. They are independent of the dose, can occur after even the first dose of the product, and are often unpredictable.
- During the examination, supervision by a physician is necessary. If hypersensitivity reactions occur, administration of the contrast agent must be discontinued immediately and – if necessary – a specific therapy must be instituted. A venous access should thus be kept during the entire examination. To permit immediate

emergency countermeasures, appropriate drugs (e.g. epinephrine and antihistamines), an endotracheal tube and a respirator should be ready at hand.

- The risk of hypersensitivity reaction may be 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)

Prior to administration of gadopiclenol**,** it is recommended that all patients are screened for renal dysfunction by obtaining laboratory tests. There have been reports of nephrogenic systemic fibrosis (NSF) associated with use of some gadolinium-containing contrast agents in patients with acute or chronic severe renal impairment (GFR < 30 mL/min/1.73 m^2). Patients undergoing liver transplantation are at particular risk since the incidence of acute renal failure is high in this group. As there is a possibility that NSF may occur with gadopiclenol, it should only be used in patients with severe renal impairment and in patients in the perioperative liver transplantation period after careful benefit/risk assessment and if the diagnostic information is essential and not available with non-contrast enhanced MRI. Haemodialysis shortly after gadopiclenol administration may be useful at removing it from the body. There is no evidence to support the initiation of haemodialysis for prevention or treatment of NSF in patients not already undergoing haemodialysis.

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 (see section 4.2).

Seizures

As with other gadolinium-containing contrast agents, special caution is necessary in patients with a lowered threshold for seizures. All equipment and drugs necessary to counter convulsions occurring during the MRI examination must be made ready for use beforehand.

Extravasation

Caution during administration is necessary to avoid any extravasation. In case of extravasation, the injection must be stopped immediately. In case of local reactions, evaluation and treatment should be carried out as necessary.

Cardiovascular disease

In patients with severe cardiovascular disease gadopiclenol should only be administrated after careful risk benefit assessment because no data are available so far.

Excipients

This medicinal product contains less than 1 mmol sodium (23 mg) per 15 mL, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

Concomitant medicinal products to be taken into account

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. The physician must obtain information before injection of gadopiclenol about the concomitant intake of those medicinal products.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no data from the use of gadopiclenol in pregnant women. Animal studies showed little placental transfer and do not indicate direct or indirect harmful effects with respect to reproductive toxicity (for details refer to section 5.3 of full prescribing information). 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. At clinical doses, no effects on the infant are anticipated due to the small amount excreted in milk and poor absorption from the gut. 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.

Fertility

Animals studies do not indicate impairment of fertility (for details refer to section 5.3 of full prescribing information).

4.7 Effects on ability to drive and use machines

Vueway has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile

The most frequent adverse reactions were injection site pain, headache, nausea, injection site coldness, fatigue and diarrhoea.

Tabulated list of adverse reactions

Table 2 below presents adverse reactions based on clinical trials including 1047 subjects exposed to gadopiclenol ranging from 0.05 mL/kg BW (equivalent to 0.025 mmol/kg BW) to 0.6 mL/kg BW (equivalent to 0.3 mmol/kg

BW). The adverse reactions are listed below by SOC (System Organ Class) and by frequency with the following guidelines: very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1 000 to < 1/100), rare (≥ 1/10 000 to < 1/1 000), very rare (< 1/10 000).

Table 2: Adverse reactions reported following gadopiclenol administration

System Organ Class	Frequency	
	Common	**Uncommon**
Immune system disorders	-	Hypersensitivity*
Nervous system disorders	Headache	Dysgeusia
Gastrointestinal disorders	-	Diarrhoea, Nausea, Abdominal pain, Vomiting
General disorders and administration site conditions	Injection site reaction**	Fatigue, Feeling hot

* Including immediate (dermatitis allergic, erythema, dyspnoea, dysphonia, throat tightness, throat irritation, paraesthesia oral and flushing) and delayed (periorbital oedema, swelling, rash and pruritus) reactions.

** Injection site reaction includes the following terms: injection site pain, injection site oedema, injection site coldness, injection site warmth, injection site haematoma and injection site erythema.

Description of selected adverse reactions

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.

Nephrogenic systemic fibrosis (NSF)

Isolated cases of NSF have been reported with other gadolinium-containing contrast agents (see section 4.4).

Paediatric population (2 years and older)

A total of 80 paediatric patients aged 2 years and older were included in the clinical trial.

As compared to adults, the safety profile of gadopiclenol in this population did not show any specific safety concern.

A total of 31 Treatment Emergent Adverse Events (TEAEs) occurred during and/or after gadopiclenol administration for 14 patients (17.5%). Twelve TEAEs were reported in the CNS cohort and 2 in the Body cohort. Among these TEAEs, 1 event in 1 patient (1.25%) from the CNS cohort was considered related to gadopiclenol.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. 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), which corresponds to 6 times the recommended dose. No signs of intoxication from an overdose have so far been reported. Gadopiclenol can be removed by haemodialysis. However, there is no evidence that haemodialysis is suitable for prevention of nephrogenic systemic fibrosis (NSF).

5. Pharmacological properties - for details please refer to full prescribing information.

6. Pharmaceutical particulars - for details please refer to full prescribing information.

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

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7 December 2023

10. DATE OF REVISION OF THE TEXT: 7 December 2023

Detailed information on this medicinal product is available on the website of the European Medicines Agency https://www.ema.europa.eu