# A. PACKAGE LEAFLET

**Package leaflet: Information for the patient**

**Vueway 0.5 mmol/mL solution for injection**
gadopiclenol

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

**Read all of this leaflet carefully before you are given this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, radiologist or pharmacist.
- If you get any side effects, talk to your doctor, radiologist or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**



## 1. What Vueway is and what it is used for

Vueway is a contrast agent which enhances the contrast of the images obtained during magnetic resonance imaging (MRI) examinations. Vueway contains the active substance gadopiclenol.

It improves the visualisation and delineation of abnormal structures or lesions of certain parts of the body and helps in the differentiation between healthy and diseased tissue.
It is used in adults and children (2 years of age and older).

It is given as an injection into your vein. This medicine is for diagnostic use only and will only be administered by healthcare professionals experienced in the field of clinical MRI practice.

## 2. What you need to know before you are given Vueway

**Vueway must not be given to you**
- if you are allergic to gadopiclenol or any of the other ingredients of this medicine (listed in section 6).

**Warnings and precautions**
Talk to your doctor, radiologist or pharmacist before you are given Vueway:
- if you had a previous reaction to any contrast agent,
- if you have asthma,
- if you have a history of allergy (such as hay fever, hives),
- if your kidneys do not work properly,
- if you had seizures (fits) or are being treated for epilepsy,
- if you have a disease affecting your heart or your blood vessels.

In all these cases, your doctor will decide whether the intended examination is possible or not. If you are given Vueway, your doctor or radiologist will take the necessary precautions and the administration of it will be carefully monitored.

Your doctor or radiologist may decide to take a blood test to check how well your kidneys are working before making the decision to use Vueway, especially if you are 65 years of age or older.

**Other medicines and Vueway**
Tell your doctor, radiologist or pharmacist if you are taking, have recently taken or might take any other medicines.
In particular, please inform your doctor, radiologist or pharmacist if you are taking or have recently taken medicines for heart and blood pressure disorders such as beta-blocking agents, vasoactive substances, angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor antagonists.

**Pregnancy and breast-feeding**

**Pregnancy**
Gadopiclenol can cross the placenta. It is not known whether it affects the baby. Tell your doctor or radiologist if you think you are, or might become pregnant as Vueway should not be used during pregnancy unless strictly necessary.

**Breast-feeding**
Tell your doctor or radiologist if you are breast-feeding or about to start breast-feeding.
Your doctor will discuss whether you should continue or interrupt breast-feeding for a period of 24 hours after you receive Vueway.

**Driving and using machines**
Vueway has no or negligible effect on the ability to drive and use machines. However, if you feel unwell after the examination, you should not drive or use machines.

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

## 3. How Vueway will be given to you

Vueway will be injected into your vein using a small needle by a specialised healthcare professional.
It can be administered by hand or by an automatic injector.

Your doctor or radiologist will determine the dose you will receive and supervise the injection.
The usual dose of 0.1 mL/kg body weight is the same in adults and children of 2 years and older.

In children, your doctor or radiologist will use Vueway in vials with a single use syringe to be able to have a better precision of the injected volume.

After the injection, you will be kept under supervision for at least 30 minutes. This is the time where most undesired reactions (such as allergic reactions) may occur. However, in rare cases, reactions may occur after hours or days.

**Use in patients with severe kidney problems**
The use of Vueway is not recommended in patients with severe kidney problems. However, if it is required you should only receive one dose of Vueway during a scan and you should not receive a second injection for at least 7 days.

**Use in elderly**
It is not necessary to adjust your dose if you are 65 years of age or older, but you may have a blood test to check how well your kidneys are working.

**If you receive more Vueway than you should**
It is highly unlikely that you will receive an overdose of Vueway, as it will be given to you by a trained healthcare professional. If it does happen, Vueway can be removed from the body by haemodialysis (blood cleaning).

If you have any further questions on the use of this medicine, ask your doctor, radiologist or pharmacist.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

After the administration of Vueway, you will be kept under observation. Most side effects occur within minutes. There is a small risk that you may have an allergic reaction to it. These effects can occur immediately and up to seven days after the injection. Such reactions can be severe and result in shock (case of allergic reaction that could put your life in danger).

**Tell your doctor, radiologist or health professional immediately if you get any of the following side effects as it may be the first signs of a shock:**
- swelling of the face, lips, tongue or throat
- lightheadedness (low blood pressure)
- breathing difficulties
- skin rash
- coughing, sneezing or runny nose

Possible side effects which have been observed during clinical trials with Vueway are listed below by how likely they are:

| **Frequency** | **Possible side effects** |
|---|---|
| **Common** (may affect up to 1 in 10 people) | Injection site reaction*<br>Headache |
| **Uncommon**<br>(may affect up to 1 in 100 people) | Allergic reaction**<br>Diarrhoea<br>Nausea (feeling sick)<br>Fatigue (tiredness)<br>Abdominal pain<br>Unusual taste in the mouth<br>Feeling of warmth<br>Vomiting (being sick) |

*Injection site reaction includes: pain, swelling, cold feeling, warm feeling, bruising or redness.
**Allergic reaction may include: inflammation of the skin, reddening of the skin, breathing difficulties, voice impairment, throat tightness, throat irritation, abnormal sensation in the mouth, transient reddening of the face (early reactions) and puffy eyes, swelling, rash and itching (late reactions).

There have been reports of nephrogenic systemic fibrosis (NSF) (which causes hardening of the skin and may affect also soft tissue and internal organs) with other contrast agent containing gadolinium however no NSF case has been reported with Vueway during the clinical trials.

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard, or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Vueway

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the vial label and the carton box after "EXP". The expiry date refers to the last day of that month.

This medicine is a clear, colorless to pale yellow solution.
Do not use this medicine if the solution is not clear or if it contains visible particles.

This medicine does not require any special storage conditions.
Chemical and physical in-use stability has been demonstrated for 24 hours at up to 25 °C. From a microbiological point of view, the product should be used immediately after opening.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

**What Vueway contains**
- The active substance is gadopiclenol. Each mL of solution contains 485.1 mg gadopiclenol (equivalent to 0.5 mmol of gadopiclenol and to 78.6 mg of gadolinium).
- The other ingredients are tetraxetan, trometamol, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment) and water for injections. See section 2 "Vueway contains sodium".

**What Vueway looks like and contents of the pack**

It is a clear, colourless to pale yellow solution for injection.

It is available in packs including:
- 1 vial containing 3, 7.5, 10, 15, 30, 50 or 100 mL of solution for injection.
- 25 vials containing 7.5, 10 or 15 mL of solution for injection.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**
Bracco UK Limited
Magdalen Centre,
The Oxford Science Park
1 Robertson Avenue,
Oxford OX4 4GA
United Kingdom

**Manufacturer**
Guerbet
16 rue Jean Chaptal
93600 Aulnay-sous-Bois France

BIPSO GmbH
Robert-Gerwig-Strasse 4
Singen (Hohentwiel)
78224
Germany

Bracco Imaging S.p.A.
Bioindustry Park, Via Ribes 5
10010 Colleretto Giacosa (TO)
Italy

**This leaflet was last revised in September 2025**

**The following information is intended for healthcare professionals only:**

For details on how to use the product, please refer to the section 6.6 Special precautions for disposal and other handling of the Summary of Product Characteristics of this product.