PRESCRIBING INFORMATION GADOBUTROL
Please refer to full national Summary of Product Characteristics (SmPC) before prescribing.
Indications and approvals may vary in different countries. Further information available on request.

PRESENTATION
Gadobutrol 1.0 mmol/mL solution for injection and solution for injection in pre-filled syringe. Solution for injection containing 604.72 mg/mL gadobutrol (equivalent to 1.0 mmol gadobutrol containing 157.25 mg gadolinium).

INDICATIONS
For diagnostic use only. Gadobutrol is indicated in adults, adolescents, and children of all ages (including term neonates) for: Contrast enhancement in cranial and spinal magnetic resonance imaging (MRI), contrast enhanced MRI of liver or kidneys in patients with high suspicion or evidence of having focal lesions to classify these lesions as benign or malignant and contrast enhancement in magnetic resonance angiography (CE-MRA) and MR Imaging of pathologies of the whole body. It facilitates visualisation of abnormal structures or lesions and helps in the differentiation between healthy and pathological tissue. Gadobutrol should be used only when diagnostic information is essential and not available with unenhanced magnetic resonance imaging (MRI).

DOSAGE AND METHOD OF ADMINISTRATION
For intravenous administration only as a bolus injection. Contrast-enhanced MRI can commence shortly after the injection depending on the pulse sequences used and the protocol for the examination. Optimal signal enhancement is observed during arterial first pass for CE-MRA and within a period of about 15 minutes after injection of Gadobutrol for CNS indications (time depending on type of lesion/tissue). T1 -weighted scanning sequences are particularly suitable for contrast-enhanced examinations. Intravascular administration of contrast media should, if possible, be done with the patient lying down. After the administration, the patient should be kept under observation for at least half an hour, since experience shows that the majority of undesirable effects occur within this time.
CNS indications: Adults: 0.1 mmol/kg BW (equivalent to 0.1 mL/kg BW). A further injection of up to 0.2 mL/kg BW may be given within 30 minutes of first injection. A dose of 0.075 mmol/kg BW (equivalent to 0.075 ml/kg BW) may be administered at minimum for imaging of the CNS.
Whole Body MRI (except MRA): Adults: 0.1 mL/kg BW.
CE-MRA: Adults: Imaging of 1 field of view (FOV): 7.5 mL for BW below 75 kg; 10 mL for BW of 75 kg and higher (corresponding to 0.1-0.15 mmol/kg BW). Imaging of > 1 field of view (FOV): 15 mL for BW below 75 kg; 20 mL for BW of 75 kg and higher (corresponding to 0.2-0.3 mmol/kg BW).
For children of all ages (including term neonates): recommended dose 0.1 mmol/kg BW (equivalent to 0.1 mL/kg BW) for all indications. The lowest dose that provides sufficient enhancement for diagnostic purposes should be used.
Please see full SmPC for further details.

CONTRAINDICATIONS
Hypersensitivity to the active substance or to any of the excipients.

WARNINGS AND PRECAUTIONS
Gadobutrol 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.
While injecting Gadobutrol into veins with a small lumen there is the possibility of adverse effects such as reddening and swelling. The usual safety requirements for magnetic resonance imaging, especially the exclusion of ferromagnetic materials applies. As with other intravenous contrast agents, Gadobutrol can be associated with anaphylactoid/ hypersensitivity or other idiosyncratic reactions, characterized by cardiovascular, respiratory or cutaneous manifestations, and ranging to severe reactions including shock. In general, patients with cardiovascular disease are more susceptible to serious or even fatal outcomes of severe hypersensitivity reactions. The risk of hypersensitivity reactions may be higher in case of previous reaction to contrast media, history of bronchial asthma or allergic disorders. In patients with an allergic disposition the decision to use Gadobutrol must be made after particularly careful evaluation of the risk-benefit ratio. Most of these reactions occur within half an hour of administration and post-procedure observation of the patient is recommended. Medication for the treatment of hypersensitivity reactions as well as preparedness for the institution of emergency measures are necessary. Delayed reactions (after hours up to several days) have been rarely observed.
Impaired renal function: **Prior to administration of Gadobutrol, 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 Gadobutrol it should therefore only be used in patients with severe renal impairment 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 magnetic resonance imaging (MRI). Haemodialysis shortly after Gadobutrol administration may be useful at removing Gadobutrol 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.

Neonates and infants: Due to immature renal function in neonates up to 4 weeks of age and infants up to 1 year, Gadobutrol should only be used in these patients after careful considerations.
Elderly: As the renal clearance of gadobutrol may be impaired in the elderly, it is particularly important to screen patients aged 65 years and older for renal dysfunction. Seizure disorders: Like with other gadolinium containing contrast agents special precaution is necessary in patients with a low threshold for seizures.

INTERACTIONS
No interaction studies have been performed.

PREGANCY AND LACTATION
Data on the use of gadolinium-based contrast agents including gadobutrol in pregnant women is limited. Gadolinium can cross the placenta. It is unknown whether exposure to gadolinium is associated with adverse effects in the foetus. Animal studies have shown reproductive toxicity at repeated high doses. Gadobutrol should not be used during pregnancy unless the clinical condition of the woman requires use of gadobutrol. 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 of breast feeding for a period of 24 hours after administration of Gadobutrol, should be at the discretion of the doctor and lactating mother.

UNDESIRABLE EFFECTS
The overall safety profile of gadobutrol is based on data from more than 6,300 patients in clinical trials and from post-marketing surveillance. The most frequently observed adverse drug reactions (≥ 0.5 %) in patients receiving gadobutrol are headache, nausea and dizziness. The most serious adverse drug reactions in patients receiving gadobutrol are cardiac arrest and severe anaphylactoid reactions (including respiratory arrest and anaphylactic shock). Delayed anaphylactoid reactions (hours later up to several days) have been rarely observed. Most of the undesirable effects were of mild to moderate intensity.
Adverse drug reactions reported in clinical trials or during post-marketing surveillance in patients treated with gadobutrol are:
Immune system disorders: Uncommon: Hypersensitivity /anaphylactoid reaction (e.g. anaphylactoid shock, circulatory collapse, respiratory arrest, pulmonary oedema, bronchospasm, cyanosis, oropharyngeal swelling, laryngeal oedema, hypotension, blood pressure increased, chest pain, urticaria, face oedema, angioedema, conjunctivitis, eyelid oedema, flushing, hyperhidrosis, cough, sneezing, burning sensation, pallor).
Nervous system disorders: Common: Headache. Uncommon: Dizziness, Dysgeusia, Paresthesia. Rare: Loss of consciousness, Convulsion, Parosmia.
Cardiac disorders: Rare: Tachycardia, Palpitations. Not known: Cardiac arrest.
Respiratory, thoracic and mediastinal disorders: Uncommon: Dyspnoea.
Gastrointestinal disorders: Common: Nausea. Uncommon: Vomiting. Rare: dry mouth.
Skin and subcutaneous tissue disorders: Uncommon: Erythema, Pruritus (including generalized pruritus), Rash (including generalized, macular, papular, pruritic rash). Not known: Nephrogenic Systemic Fibrosis (NSF).
General disorders and administration site conditions: Uncommon: Injection site reaction, Feeling hot. Rare: Malaise, Feeling cold. Reports of life-threatening and/or fatal outcomes for some of the ADRs, please see full SmPC for more information.

OVERDOSE
The maximum daily single dose tested in humans is 1.5 mmol gadobutrol/kg body weight. No signs of intoxication from an overdose have so far been reported during clinical use. In case of inadvertent overdosage, cardiovascular monitoring (including ECG) and control of renal function is recommended as a measure of precaution. In case of overdose in patients with renal insufficiency, Gadobutrol can be removed by haemodialysis. After 3 haemodialysis sessions approx. 98 % of the agent are removed from the body. However, there is no evidence that haemodialysis is suitable for prevention of nephrogenic systemic fibrosis (NSF).

INSTRUCTIONS FOR USE AND HANDLING
For single use only. This medicinal product should be visually inspected before use. Gadobutrol should not be used in case of severe discoloration, the occurrence of particulate matter or a defective container. If this medicinal product is intended to be used with an automatic application system, its suitability for the intended use has to be demonstrated by the manufacturer of the medicinal device. Any additional instructions from the respective equipment manufacturer must also be strictly adhered to. The peel-off tracking label on the vials/bottles should be stuck onto the patient record. The dose used should also be recorded. If electronic patient records are used, the name of the product, the batch number and the dose should be entered into the patient record. See full SmPC for more information.

MARKETING AUTHORISATION HOLDER
GE Healthcare Limited, Pollards Wood, Nightingales Lane, Chalfont St Giles, Buckinghamshire,
HP8 4SP, United Kingdom

CLASSIFICATION FOR SUPPLY
Subject to medical prescription

UK MARKETING AUTHORISATION NUMBER
PL 00221/0400 and PL 00221/0401.

DATE OF REVISION OF THE TEXT
Date of revision of text: (February 2026), based on SmPC dated (May 2024).

PRICE
10x7.5ml: £506.3

Adverse events should be reported.
Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/.
Adverse events should also be reported to GE HealthCare at gpv.drugsafety@gehealthcare.com.