UJ GADO - M

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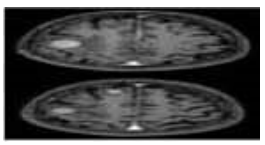
"From Farm to Pharma"
Webs: www.unijules.com, www.contrastmedia.in

Meglumine Gadoterate Injection
0.5 mmoL/mL
(376.9 mg/mL)



Axial CE-T1 weighted image after iv administration of gadoteric acid in a patient with renal impairment and cerebral metastasis on right frontal lobe (3 - Tscan)

Most trusted and dependable

A paramagnetic macrocyclic ionic contrast medium for use in MRI.

- Gadolinium ion forms a stable complex with DOTA as chelating agent.
- 100 % Renally excreted.
- T1 Relaxivity at 1.5 T : 3.4 - 3.8L / mmoles (slightly lower than other extracellular contrast agent)
- Suitable for all age groups including neonates and elder patients.
- Good choice for patients with lower GFRs.
- Efficacy & safety of Gadoterate Meglumine evaluated in a multi- center clinical trial studies.
- Easy to detect and visualize areas with disruption of blood brain barrier or abnormal vascularity.
- Gadoterate Meglumine does not cross the intact blood brain barrier and hence does not effect or enhance normal brain tissue.
- Gadoterate Meglumine has minimal effects on blood pressure and heart rate.

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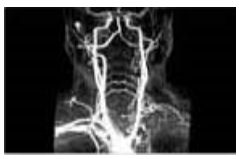
Composition	Each ml Gadoterate Meglumine Injection contains 376.9 mg Gadoterate Meglumine equivalent 279.32 mg gadoteric acid.		
Pack	10 ml	15 ml	20 ml
Total Concentrate of Gadoterate Meglumine	3.769 g (5 mmol/10 ml)	5.654 g (7.5mmol/15mL)	7.538g (10 mmol/20 ml)
Density @ 20°C	1.1753 g/ml	1.1753 g/ml	1.1753 g/ml
pH	7.3 ± 0.2		
Viscosity @ 20°C @ 37°C	3.4 mPas 2.4 mPas		
Osmolality at 37°C	1350 mOsm/kg water		



Maximum intensity projection reconstructed image of contrast - enhanced magnetic resonance angiography of epiaortic vessels.

WARNING AND PRECAUTIONS

- Nephrogenic systemic fibrosis : Gadolinium based contrast agents increase the risk of NSF among patients with impaired elimination of drug. Screen patients for acute kidney injury and other condition that may reduce renal function.
- To be administered only by intravenous route.
- Gadoteric acid must not be administered by subarachnoid (or epidural) injections.
- Before any contrast medium is injected, the patient should be questioned for a history of allergy (e.g. seafood allergy, hay fever, hives), sensitivity to contrast media and bronchial asthma as the reported incidence of adverse reactions to contrast media is higher in patients with these conditions and premedication with antihistamines and/or glucocorticoids may be considered.
- During the examination, supervision by a physician is necessary. If hypersensitivity reactions occur, administration of the contrast medium must be discontinued immediately and if necessary specific therapy instituted. A venous access should thus be kept during the entire examination. To permit immediate emergency countermeasures, appropriate medicinal products (e.g. epinephrine and antihistamines), an endotracheal tube and a respirator should be ready on hand.
- There are no data from the use of Meglumine Gadoterate Injection in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity . Meglumine Gadoterate Injection not be used during pregnancy unless the clinical condition of the woman requires use of gadoteric acid.
- Gadolinium containing contrast agents are excreted into breast milk in very small amounts. .

ADVERSE REACTION

Organ Class System	Frequency: adverse reaction
Immune system disorder	Uncommon: Hypersensitivity, Anaphylactic reaction
Sychiatric disorders	Very rare: Agitation, Anxiety
Nervous system disorders	Very common: Paraesthesia, Headache Rare: Dysgeusia Very rare: Coma, Convulsion, Syncope, Presyncope, Dizziness, Parosmia, Tremor
Eye disorders	Very rare: Conjunctivitis, Ocular hyperaemia, Vision blurred, Lacrimation increased, Eyelid edema
Cardiac disorders	Very rare: Cardiac arrest, Bradycardia, Tachycardia, Arrhythmia, Palpitations
Vascular disorders	Very rare: Hypotension, Hypertension, Vasodilatation, Pallor
Respiratory, thoracic and mediastal disorders	Very rare: Respiratory arrest, Pulmonary oedema, Bronchospasm, Laryngospasm, Pharyngeal oedema, Dyspnoea, Nasal congestion, Sneezing, Cough, Dry throat
Gastrointestinal disorders	Common: Nausea, Vomiting Very rare: Diarrhoea, Abdominal pain, Salivary hypersecretion
Skin and subcutaneous tissue disorders	Common: Pruritus, Erythema, Rash Rare: Urticaria, Hyperhidrosis, Very rare: Eczema, Angioedema Not known: Nephrogenic systemic fibrosis
Musculoskeletal and connective tissue disorders	Very rare: Muscle contracture, Muscular weakness, Back pain
General Disorders and administration site conditions	Common: Feeling hot, Feeling cold, Injection site pain Very rare: Malaise, Thoracic pain, Chest discomfort, Fever, Chills, Face oedema, Asthenia, Injection site discomfort, Injection site reaction, Injection site oedema, Injection site extravasation, Injection site inflammation (in case of extravasation), Injection site necrosis (in case of extravasation), Superficial phlebitis
Investigations	Very rare: Decreased oxygen saturation
Blood and lymphatic system disorders	Haemolysis
Renal and urinary disorders	Urinary incontinence, Renal tubular necrosis, Renal failure acute

DOSAGE AND ADMINISTRATION

Adult and pediatric patients recommended dose is 0.2 mL/kg (0.1 mmol/kg) body weight administered an intravenous bolus injection at a flow rate approx 2 mL/sec for adult and1-2 mL/sec for pediatric patients.

INDICATIONS

CE- Perfusion MRI (Brain lesions MRI)
Functional CE-MRI techniques such as perfusion weighted imaging are in routine use for neuroimaging, most notably for the evaluation and grading of brain lesions. The most common application of CE-MRI is in the evaluation of primary and secondary brain tumors.

MR Angiography
Gadoteric acid is also used in MRA for study of supraaortic vessels, and CMR is employed in the detection of chronic myocardial infarctions.
MRA is a noninvasive and reliable tool for imaging blood vessels.

Cardiac MRI
Cardiac MRI is a well -established modality in the diagnosis of myocardial infarction because this disease can be difficult to diagnose clinically. Myocardial infarction is identified by late gadolinium enhancement, after iv administration of gadolinium chelates.

Spinal lesions MRI
Gadoteric acid is the only macrocyclic and ionic GBCA commercially available. It is indicated for intravenous use with MRI of the brain, spine, and associated tissues in adult and pediatric patients (2 years of age and older) to detect and visualize areas with disruption of the BBB and/or abnormal vascularity.

Body MRI
Gadoteric acid is also used for body CE-MRI, particularly for imaging of breast and pancreas and for all patients with renal impairment who cannot undergo CE-MRI scan with higher concentrated contrast agents.
Breast MRI is a well-consolidated diagnostic technique, with precise indications in the breast cancer field. The use of a paramagnetic contrast medium allows the study of breast mass vascularization and tumor neoangiogenesis.
Breast MRI is performed using a 1.5 T system with a specific surface coil for breast examination.

CONTRAINDICATION

Hypersensitivity to gadoterate meglumine or to any product containing gadolinium.

OVERDOSE

Gadoteric acid can be removed by haemodialysis. However there is no evidence that haemodialysis is suitable for prevention of nephrogenic systemic fibrosis (NSF).

STORAGE

Store at temperature not exceeding 30°C. Do not freeze . Protect from light. Keep out of reach of children.

PRESENTATION

10 ml ,15 ml and 20 ml vials

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