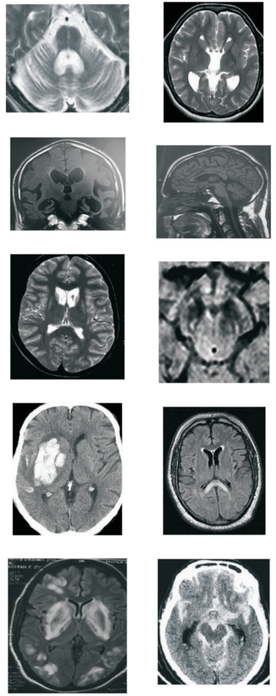
Magnitect

A Paramagnetic Contrast Medium for use in MRI

- **Exceptional in vivo stability**
- **High LD50**
- **Facilitates Optimum Diagnosis**
- **Widest Indications**
- **PROVEN safety profile in all ages including pediatric segment**

Excluding Heart
* Paediatric : 2 Years of age and older
Magnitect offers broadest range of adult & paediatric indications (CNS, HEAD, NECK & BODY) of any MRI contrast agent



Magnitect 10 ml & 20 ml

Gadopentetate Dimeglumine Injection

Compositoin :

Each ml Magnitect injection contains 469 mg (0.5 mol/l) gadopentect acod dimeglumine salt in aqueous solution.

Magnitect is indicated in adults and children 2 years of age and older to provide contrast enhancement during magnetic resonance imaging (MRI) of intracranial lesions with abnormal vascularity or those suspected of causing an abnormality in the bold-brain barrier. Magnitect enhanced MRI helps in the diagnosis and characterization of neoplasitic disease, acoustic neuroma, subacute infarction, inflammatory disease, certain vascular abnormalities and certain demyelinating abnormalities (e.g. multiple sclerosis). Magnitect is used in amgnetic resonance (MR) studies to help differentiate changes that occur secondary to brain tumor resection (e.g. encephalomalaica, gliosis) or to postoperative irradiation or chemotherapy (e.g. edema, ischemia, demyelination, necrosis) from changes that represent residual or recurrent tumors to accurately assess treatment results. MRI with magnitect is particularly useful in patients with normal unenchanted studies who have centra nervous system (CNS) symptoms, in patients with CNS tumors that are difficult to separate from surrounding edema and in patients who have undergone surgery to differentiate recurrence of the lesions from postoperative changes. In patients with suspected meningitis. Magnitect enhance MRI may be particularly useful in defining the active inflammatory process of the meninges and focal lesions.

Spinal Lesions MRI :

Magnitect in indicated in adults and children 2 years of age and older to provide contrast enhancement and facilitate visualization of lesions in the spine and associated tissues. Magnitect provides enhanced contrast of epidural abscesses, which makes it possible to differentiate them from adjacent compressed thecal sac. It facilitates the diagnosis of disk space infection and osteomylitis. It helps localize portions of paraspinal masses most likely to yield a positive percutaneous biopsy and it helps distinguish active spinal infections from those that have responded adequately to antibiotic therapy.

MRI with Magnitect may be useful in differentiating postoperative epidural fibrosis (scar tissue) from recurrent disk herniation in patients with symptoms of failed back surgery syndrome to avoid unnecessary and possibly damaging reoperation if scar tissue is the cause.

Whole Body MRI :

Magnitect is indicated in adults to improve lesion contrast during MR body imaging (excluding the heart) in the evaluation of suspected hepatic lesions, endometrial or cervical carcinomas or pelvic masses, breast lesions (suspected or known), and musculoskeletal lesions. MRI of the breast is also used in patients with postoperative scarring and silicon implants to exclude or demonstrate.

Cardiac MRI :

Magnitect enhanced MRI is used in the evaluation of patients with great vessel disease (e.g. aortic aneurysm, aortic dissection, congenital abnormalities, vena cava obstruction): in patients with ischemic cardiac disease to examine the heart for regions of wall thinning and intracardiac thrombus to assess chamber size, myocardial mass, wall motion, and wall thickning and to detect regions of acute infarction; and in patients with congenital heart disease to evaluate malrotations of the heart and for post-surgery assessment. Also Magnitect enhanced MRI helps in the assessment of coronary artery reperfusion after thrombolysis.

ADVERSE REACTIONS :

Cardiovascular : Hypotension, vasodilation, pallor, phlebitis, nonspecific ECG changes, substemal pain, angina.

GNS : headache, dizziness, agitation, paresthesia tinnitus, visual field defect, convulsions, hypersthesia.

Gastrointestinal : nausea, vomiting, gastointestinal distress, stomach pain, thirst, increased salivation, taste abnormality.

Respiratory : dry mouth, throat imitation, rhinorrhea, wheezing, laryngismus, cough, dyspnea/apnea.

Cutaneous / Mucous Membranes : rash, sweating, urticaria, pruritus.

Miscellaneous : injection site discomfort (coldness, burning, warmth, pain), toothache, generalized weakness, fever localized edema, tiredness, anaphylactoid reactions (characterized by cardiovascular, respiratory and cutaneous symptoms), conjunctivitis.

Composition	MAGNITECT
Concentration	469 mg /nl
pH	6.5-8.0
Viscosity (mPa*)s@37°C	2.9
Viscosity (mPa*)s@20°C	2.9
Osmolality (mOsm/g H2O) 37°C	1.96

PRECAUTIONS :

General

Magnitect is to be administered strictly by i.v. injection. It will cause tissue irritation and pain if administered extravascularly or if it leaks interstitially.

A sweet taste may be experienced briefly by patients receiving a bolus injection of Magnitect iv. Pregnancy / Reproduction Pregnancy.

Adequate and well-controlled studies in humans have not been done. Although there if no evidence that the magnetic and electric fields associated with MRI have an effect on human development, in vitro studies and theoretical predictions raise concern regarding the risk of exposure to MR to the developing embryo and foetus. More studies are needed to establish the safety of MRI in pregnant patients.

Studies in rats with Magnitect at doses 2.5 times and in rabbits at doses 7.5 & 12.5 times the human dose have shown that this agent causes slight retardation in development.

Breast-feeding

Problems in humans have not been documented. Since Magnitect is distributed in small amounts into breast milk, temporary discontinuation of breast-fedding should be considered for at least 24 hours following its administration.

DOSAGE AND ADMINISTRATION :

General instruction

1. Patient should be on fast for at least 2 hrs before the examination.
2. The drug is given as bolus injection and can be followed by contrast enhanced MRI
3. Magnitect should not be drawn into the syringe until immediately before use. Any unused portion must be discarded on completion of the procedure.
4. The patient should be in supine position while administering the injection and should be kept under supine position for at lease half an hour after the injection.
5. Do not use the solution if it is discoloured or particulate matter is present.
6. The imaging procedure should be completed within 1 hour since optimal contrast is generally observed in cranial investigations within 27 minutes following injection of Magnitect and in spinal investigations during the early postadministration phase (10 to 30 minutes). The following dosage guidelines apply to adults and children (above 2 years).
7. Recommended Dose : 0.2 ml / kg b.w. (0.1 mmol / kg. b.w.).
8. Route of Administration : I.V. (into a large vein, if possible).
9. Rate of Administration : 10 ml / minute or as a bolus injection at 10 ml / i 5 seconds.
10. Maximum Total Dose : 20 ml.

To ensure complete injection of the contrast medium the injection should be followed by a 5m 1 normal saline flush if strong clinical suspicion of an intracranial or intraspinal lesion persists despite a normal MRI scan the diagnostic yield of the examination may be giving another injection of Magnitect equivalent to the original total dose within 30 minutes and performing MRI again.

OVERDOSAGE :

Systemic consequences of overdose with Magnitect have not been reported

CONTRAINDICATIONS :

1. Magnitect should not be administered to patients with known or suspected hypersensitivity to Gadopentetate Dimeglumine.
2. Renal failure.
3. Sickle cell anaemia.

STORAGE :

Store at controlled room temoerature 20°C to 30°C. Do not freeze. Protect from direct sunlight, inspect container for particulate matter before use. Discard unused portion.

Available Packing Information

Presentations	Code
Magnitect 10 ml	MT 10
Magnitect 20 ml	MT 20