GADOSOL

GADOTERIC ACID

Compositions:
Gadosol 0.5 mmol/ml solution for injection: Each 1 ml solution for injection contains 279.32 mg of gadoteric acid (as meglumine salt), equivalent to 0.5 mmol of gadoteric acid (as meglumine salt).

Pharmacology:
Gadoterate is a paramagnetic molecule that develops a magnetic moment when placed in a magnetic field. The magnetic moment enhances the relaxation rates of water protons in its vicinity, leading to an increase in signal intensity (brightness) of tissues. When placed in a magnetic field, gadoterate shortens the T1 and T2 relaxation times in target tissues.

Dosage And Administration:
For adult and pediatric patients (including term neonates), the recommended dose of Gadosol is 0.2 mL/kg (0.1 mmol/kg) body weight administered as an intravenous bolus injection, manually or by power injector, at a flow rate of approximately 2 mL/second for adults and 1-2 mL/second for pediatric patients. Table 1 provides weight-adjusted dose volumes. Table 1: Volumes of Gadosol Injection by Body Weight   Body Weight Volume Pounds (lb) Kilograms (kg) Milliliters (mL) 5.5 2.5 0.5 11 5 1 22 10 2 44 20 4 66 30 6 88 40 8 110 50 10 132 60 12 154 70 14 176 80 16 198 90 18 220 100 20 242 110 22 264 120 24 286 130 26 308 140 28 330 150 30   To ensure complete injection of Gadosol the injection may be followed by normal saline flush. Contrast MRI can begin immediately following Gadosol injection.

Contraindications:
undefined

Warning And Precaution:
Nephrogenic Systemic Fibrosis has occurred in patients with impaired elimination of GBCAs. Higher than recommended dosing or repeat dosing appear to increase the risk. Hypersensitivity: Anaphylactoid/anaphylactic reactions with cardiovascular, respiratory or cutaneous manifestations, ranging from mild to severe, including death, have uncommonly occurred. Monitor patients closely for need of emergency cardiorespiratory support.

Side Effects:
The most frequent adverse reactions in clinical studies were nausea, headache, injection site pain, injection site coldness, and burning sensation.

Use in Pregnancy and Lactation:
Pregnancy: Pregnancy Category C. There are no adequate and well-controlled studies with Gadosol conducted in pregnant women. Limited published human data on exposure to other GBCAs during pregnancy did not show adverse effects in exposed neonates. No effects on embryo fetal development were observed in rats or rabbits at doses up to 10 mmol/kg/day in rats or 3 mmol/kg/day in rabbits. The doses in rats and rabbits were respectively 16 and 10 times the recommended human dose based on body surface area. Gadosol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.   Lactation: It is not known whether Gadoteric Acid is excreted in human milk. Limited case reports on use of GBCAs in nursing mothers indicate that 0.01 to 0.04% of the maternal gadolinium dose is excreted in human breast milk. Because many drugs are excreted in human milk, exercise caution when Gadoteric Acid is administered to a nursing woman. Nonclinical data show that gadoterate meglumine is excreted into breast milk in very small

amounts (< 0.1% of the dose intravenously administered) and the absorption via the gastrointestinal tract is poor.

Drug Interaction:
undefined

Overdosage:
In the real case of overdose, Gadosol can be removed from the body by haemodialysis (blood cleaning).

Storage:
Store at 25°C; Should solidification occur in the vial because of exposure to the cold, Gadoteric Acid should be brought to room temperature before use. If allowed to stand at room temperature for a minimum of 90 minutes, Gadoteric Acid should return to a clear, colorless to yellow solution. Before use, examine the product to assure that all solids are redissolved and that the container and closure have not been damaged. Should solids persist, discard the vial.

Packing:
Gadosol 0.5 mmol/ml solution for injection: Each box contains 1 vial of 10 ml Gadoteric Acid injection.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.