

# OptiMARK®

## Gadoversetamide Injection



### Description

**The only MR contrast agent FDA-approved for administration by power injector**, OptiMARK® is a gadolinium based, IV contrast media for MR imaging of the brain, spine and liver. OptiMARK® has convenient packaging options for just the right amount of contrast, packaged for efficient, problem-free delivery. You can trust OptiMARK® for the tolerability and diagnostic accuracy you expect from a gadolinium extracellular contrast agent. Extensive clinical trials have demonstrated safety, including in patients with renal insufficiency (n=28).

### OptiMARK® Safety Updates

Nephrogenic Systemic Fibrosis

### Features and Benefits

- Non-Ionic, Low Osmolar
- Single-dose vials in a range of sizes
- Convenient multi-dose bottle for less wasted contrast
- Demonstrated efficacy for brain, spine and liver
- The first and only MRI agent approved for power injection
- A selection of pre-filled plastic syringes for safer and easier injections
- OptiMARK® pre-filled syringes meet the new JCAHO 2004 medication management standards for accreditation
- OptiMARK® pre-filled syringes meet OSHA's Bloodborne Pathogen Standards
- OptiMARK® pre-filled syringes adhere to the Needlestick Safety and Prevention Act
- OptiMARK® pre-filled syringes are latex-free

### Indications and Applications

OptiMARK® is indicated for brain, spine, and liver imaging. OptiMARK® also has a power injector indication.

### Important Safety Information

Caution is needed in patients with sickle cell anemia. Deoxygenated sickle erythrocytes have been shown in vitro studies to align perpendicular to a magnetic field; this may result in vaso-occlusive complications in vivo. The enhancement of magnetic moment by gadoversetamide may potentiate sickle erythrocyte alignment. Patients with history of allergy, renal insufficiency or drug reactions should be observed for several hours after drug administration. OptiMARK injection in patients with sickle cell anemia and other hemoglobinopathies has not been studied.

CAUTION SHOULD BE EXERCISED WHEN A CONTRAST ENHANCED INTERPRETATION IS MADE IN THE ABSENCE OF A COMPARISON UNENHANCED MRI. Since gadoversetamide is cleared renally, caution should be exercised in patients with impaired renal function. The possibility of a reaction, including serious, life threatening, fatal, anaphylactoid or cardiovascular reactions or other idiosyncratic reactions should always be considered especially in those patients with a known clinical hypersensitivity, a history of asthma, or other respiratory disorders. The most common adverse events were headache, vasodilation, taste perversion, dizziness, nausea and paresthesia.

#### **Distribution**

Direct or Distributor - M/s. **ADITHI MED X SOLUTIONS** – Karnataka, India

#### **Package Description**

Choose the package that fits the need, either in glass vials (with a large range of sizes) or Ultraject® pre-filled plastic syringes. These syringes are safe and easy to use for power injectors or handheld use. OptiMARK® is conveniently packaged in the largest variety of plastic pre-filled syringes. OptiMARK® also offers the flexibility of pharmacy bulk package with the 50 mL vial available for multiple single dose preparations.