

Prescribing information

Optimark™ gadoversetamide 500 micromol/ml solution for injection in a vial or a pre-filled syringe ▼

Abbreviated prescribing information. Please refer to the Summary of Product Characteristics before prescribing. **COMPOSITION:** 1 ml contains 330.9 mg gadoversetamide, equivalent to 500 micromol. ▼ **INDICATIONS:** For diagnostic use only. For use with magnetic resonance imaging of the central nervous system (CNS) and liver. Provides contrast enhancement and facilitates visualisation of lesions and helps with the characterisation of focal lesions and abnormal structures in the CNS and liver in patients with known or highly suspected pathology. **DOSAGE, METHOD OF USE, AND ROUTE OF ADMINISTRATION:** Optimark should only be administered by physicians experienced in clinical MRI practice. The agent should be administered as a bolus peripheral intravenous injection at a dose of 0.2 ml/kg (100 micromol/kg) body weight. The imaging procedure should be completed within 1 hour of administration. In cranial MRI, a second bolus of injection may be administered 30 minutes after the first which may increase the diagnostic yield of the examination. The safety of repeat doses has not been established in children and adolescents, the elderly and in renal impairment. Optimark is not recommended for use in children below the age of 2 years. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or any of the excipients or to other Gadolinium-containing products. Patients with severe renal impairment (GFR <30ml/min/1.73m²), and those who have had or are undergoing liver transplantation. **SPECIAL WARNINGS AND PRECAUTIONS FOR USE:** As with any paramagnetic contrast agent, enhancement of MRI with gadoversetamide may impair the visualisation of existing lesions. Patients need to be sufficiently hydrated. Supervision by a physician is necessary and insertion of a flexible in-dwelling catheter is recommended. The usual contraindications for MR examinations should be applied. In case of hypersensitivity reactions, discontinue immediately and initiate intravenous treatment as necessary (e.g. epinephrine/adrenaline, theophylline, antihistamines, corticosteroids and atropines), endotracheal tube and ventilator. Ascertain patient allergy, hypersensitivity and asthma history prior to injection. Premedication with antihistamines and/or glucocorticoids may be considered. Hypersensitivity reactions may be more severe in patients with cardiovascular disease. Patients using beta-blockers may not respond to beta-agonists. In patients suffering from epilepsy or brain lesions the likelihood of convulsions during examination may be increased. There have been reports of nephrogenic systemic fibrosis (NSF) associated with some gadolinium

containing contrast agents in patients with severe renal impairment (GFR<30ml/min/1.73m²) and those who have had or are undergoing liver transplantation. Cases of NSF have also been reported in patients with moderate renal impairment (GFR<60ml/min/1.73m²). Optimark should be used in these patients with caution. Optimark must not be administered with an autoinjector in children to avoid the possibility of overdose. Optimark should not be used in children below the age of two years. Doses greater than 17 ml contain 1 mmol of sodium or more, which should be taken into consideration for patients on a controlled sodium diet. Transient decreases in serum iron and zinc parameters have been observed in clinical trials. The clinical significance of this is unknown. **INTERACTIONS:** No formal studies have been performed. **PREGNANCY AND LACTATION:** Optimark should not be used during pregnancy unless a contrast enhanced MR is critical. Optimark can be used during breastfeeding. **UNDESIRABLE EFFECTS:** Most undesirable effects are mild to moderate intensity and transient in nature. The most common are dysgeusia, feeling hot, headache and dizziness. Local reactions have occurred at the injection site. Serious adverse reactions have been reported and include anaphylactic reactions, cardiovascular reactions, and allergic respiratory disorders. Immediate access to necessary medicinal products and emergency equipment should be available. Prescribers should consult the SPC for further details. **LEGAL STATUS:** Prescription only. **DATE OF PREPARATION:** November 2007. **MARKETING AUTHORISATION HOLDER:** Tyco Healthcare Deutschland GmbH, Gewerbepark 1, 93333 Neustadt/Donau, Germany. **MARKETING AUTHORISATION NUMBERS:** EU/1/07/398/002 EU/1/07/398/004 EU/1/07/398/006 EU/1/07/398/008 EU/1/07/398/010 EU/1/07/398/012 EU/1/07/398/014

PRICE: 15ml syringe; 10 x 15ml £600.00 excl. VAT. **ADVERSE EVENT REPORTING:** Information regarding adverse event reporting can be found at www.yellowcard.gov.uk. Adverse events should also be reported to Covidien (UK) Commercial Ltd, 154 Fareham Road, Gosport, Hampshire, PO13 0AS Tel: 01329 224000. **FURTHER INFORMATION AVAILABLE FROM:** Covidien (UK) Commercial Ltd, (formerly Tyco Healthcare).

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A Complete MRI Contrast Medium Delivery Solution
Optimark™ gadoversetamide ▼ contrast medium for MR imaging
of the CNS and Liver and Optistar™ LE power injector

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Formerly Tyco Healthcare

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References:

1. Data on file, MRI Radiologist Survey, 2007.
2. Rubin DL et al. JMIR 1999;9:240-250.
3. Optimark Summary of Product Characteristics.
4. European Medicines Agency. Optimark European Public Assessment Report. Scientific Discussion.
5. Swan SK et al. JMIR 1999;9:317-321.



A complete MRI contrast medium delivery solution



Your needs

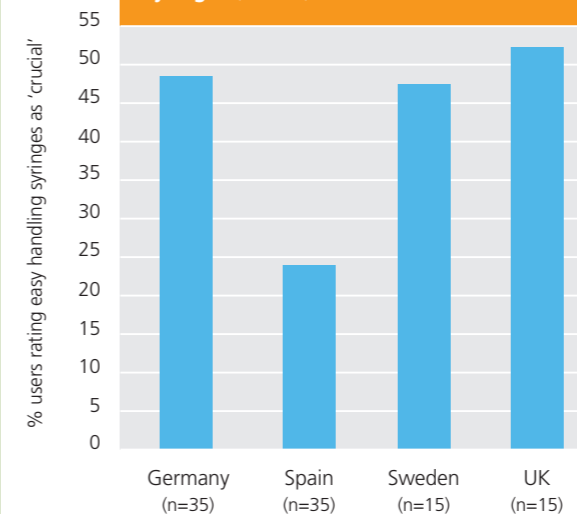
What do you look for in a gadolinium-based MRI contrast agent?

- A large proportion of users rate easy to handle syringes as 'crucial'^{**}
- Easy to handle injection devices were also rated as 'crucial'^{**}

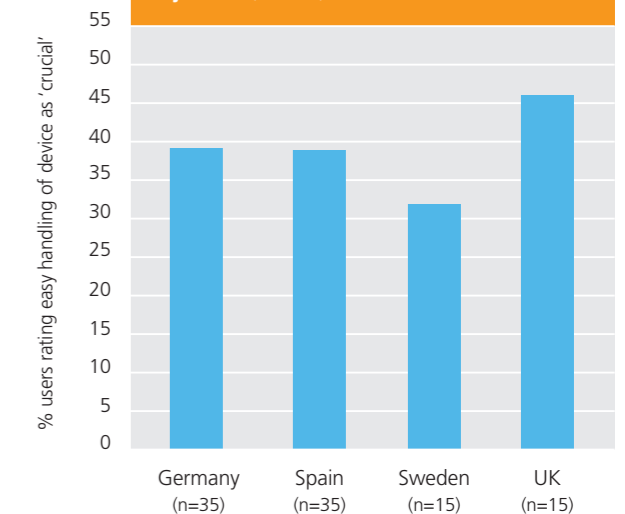
* When asked to rate product aspects as 'doesn't matter', 'also matters', or 'crucial' when opting for a gadolinium-based MRI contrast agent.

Optimark gadoversetamide ▼ contrast medium pre-filled syringes are easy to prepare as they require no filling from vials.

The importance of easy to handle syringes (n=100)



The importance of easy to handle injection (n=100)



Adapted from data on file¹
Refer to back cover for Optimark contrast medium prescribing information.

Totally integrated

Perfect fit

Optimark™ contrast medium

- Drop-in syringe loading is easy and convenient.
- Automatic syringe size detection.
- 'Check for air' safety check feature.
- **Optimark contrast medium should not be administered to children using an auto injector.**



Refer to back cover for Optimark contrast medium prescribing information.

Easy handling

Optistar™ LE power injector

Easy touch screen operation

- Full colour touch screen for easy visibility.
- Store up to 20 of your own protocols to enhance efficiency.

Real-time injection progress

- Injection indicator displays volume to be delivered.
- Monitors delivery pressure during injection.

Battery free

- No time-consuming battery maintenance.

Optimark contrast medium and Optistar LE power injector system – two components of a total MRI delivery solution.

Fast preparation

Optimark contrast medium pre-filled syringes are simple to use and quick to load into the Optistar LE power injector compared to non pre-filled syringes.

- Drop the syringe into power head and click into place.
- No need to fill empty syringes from vials.
- No need for additional empty syringes when using Optimark pre-filled syringes.
- Attach tubing and prime.
- Check for air and enable the system.
- Attach patient line to cannula.
- Select protocol.
- Start injection when ready.

Using Optistar LE and Optimark contrast medium is so intuitive, it will quickly fit into your daily practice.



Similarly effective

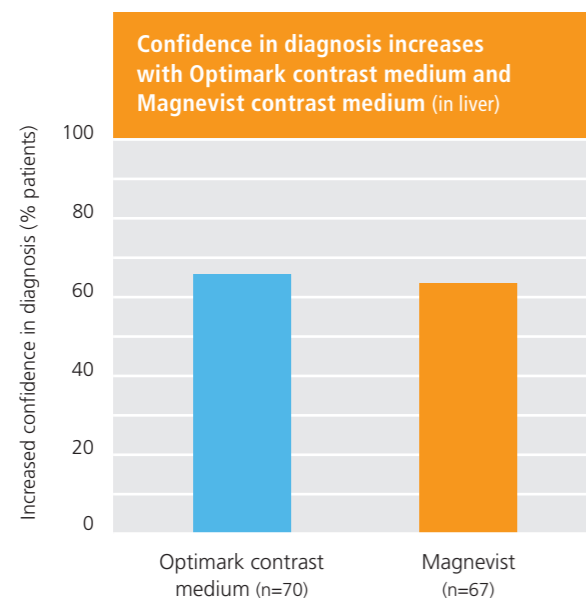
Optimark contrast medium is similarly effective as Magnevist*² in liver MRI.

Results from a Phase III clinical trial in patients with liver pathology (n=193):

- Use of both Optimark contrast medium and Magnevist* significantly increased confidence in lesion diagnosis² compared to pre-contrast scans.

* Magnevist is a registered trademark of Bayer Schering Pharma AG.

As of December 2006, more than 4.4 million doses of Optimark contrast medium have been administered to patients, worldwide.⁴



Adapted from Rubin et al., 1999.

Well characterised

Optimark contrast medium is generally well tolerated.

- A multi centre, double-blind, randomised, placebo controlled trial found Optimark contrast medium to be generally well tolerated in subjects with either liver or CNS pathology.⁵
- In the 0.1 mmol/kg dose group, all adverse events were considered mild or moderate in severity.⁵

Contraindications

- Hypersensitivity to gadoversetamide, excipients or gadolinium products.
- Patients with severe renal impairment (GFR<30ml/min/1.73m²) and those who have had or are undergoing liver transplantation.

Special warnings and precautions

- As with any paramagnetic contrast agent, enhancement of MRI with gadoversetamide may impair the visualisation of existing lesions. Some of these lesions may be seen on unenhanced, non-contrast MRI. Therefore, caution should be exercised when contrast enhanced scan interpretation is made in the absence of a companion unenhanced MRI.
- Hydration is important prior to the examination. The usual contraindications of MR examinations must be applied, such as exclusion of patients with infusion pumps, pacemakers, ferro-magnetic clips etc.
- Hypersensitivity- please refer to SPC.
- Renal Impairment- please refer to SPC.³
- Most common adverse events: dizziness, headache, dysgeusia, feeling hot.
- Serious adverse reactions have been reported and include anaphylactic reactions, cardiovascular reactions, and allergic respiratory disorders.
- Cases of Nephrogenic Systemic Fibrosis (NSF) have been reported.³

Optimark contrast medium



Packaging	Size	Product Code
Pre-filled syringe x10	10ml	1177EX10
	15ml	1177EX15
	20ml	1177EX20
	30ml	1177EX30
Glass vial x10	10ml	1177EX04
	15ml	1177EX06
	20ml	1177EX08

Optimark contrast medium combined with the Optistar LE power injector provides a complete MRI delivery solution.

Totally integrated

- A complete delivery system designed to fit into your daily practice.

Complete synergy

- Easy and convenient, with an intuitive user interface.

Perfect partnership

- Optimark contrast medium pre-filled syringes have been designed so that they can be used with Optistar LE power injector.