Mallinckrodt Pharmaceuticals

Optimark™ (gadoversetamide injection)

This information is intended for U.S. healthcare professionals only.

Gadolinium-based contrast agents (GBCAs) increase the risk for NSF among patients with impaired elimination of the drugs. Avoid use of GBCAs in these patients unless the diagnostic information is essential and not available with non-contrasted MRI or other modalities. NSF may result in fatal or debilitating fibrosis affecting the skin, muscle and internal organs.

INDICATIONS AND USAGE

Optimark (gadoversetamide injection) injection is a contrast agent indicated for use with magnetic resonance imaging (MRI) in patients with abnormal blood-brain barrier or abnormal vascularity of the brain, spine, and associated tissues. It is also indicated for use with MRI to provide contrast enhancement and facilitate visualization of lesions with abnormal vascularity in the liver in patients who are highly suspect for liver structural abnormalities on computed tomography.

IMPORTANT RISK INFORMATION

WARNING: NEPHROGENIC SYSTEMIC FIBROSIS

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- Do not administer Optimark to patients with:
  - chronic, severe kidney disease (GFR <30 mL/min/1.73m2), or
  - acute kidney injury
- Screen patients for acute kidney injury and other conditions that may reduce renal function. For patients at risk for chronically reduced renal function (e.g. age >60 years, hypertension or diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing.
- Do not exceed the recommended Optimark dose and allow a sufficient period of time for elimination of the drug from the body prior to any re-administration.

CONTRAINDICATIONS

- Optimark is also contraindicated in patients with:
  - Known allergic or hypersensitivity reactions to gadolinium, versetamide or any of the inert ingredients.

WARNINGS AND PRECAUTIONS

- Gadolinium-based contrast agents (GBCAs) increase the risk for nephrogenic systemic fibrosis (NSF) in patients with impaired elimination of the drugs. mL/min/1.73m2) and patients with acute kidney injury. Do not administer Optimark to these patients.
- Screen patients for acute kidney injury and other conditions that may reduce renal function. Serum creatinine levels and estimated GFR may not reliably assess renal function in the setting of acute kidney injury. For patients at risk for chronic

kidney disease (e.g., age >60 years, diabetes mellitus or chronic hypertension), estimate the GFR through laboratory testing.

- When administering Optimark, do not exceed the recommended dose and allow a sufficient period of time for elimination of the drug prior to any re-administration. Record the specific GBCA and the dose administered to a patient.
- The potential risk of hemolysis after injection of Optimark Injection in patients with other hemolytic anemias has not been studied.
- Patients with history of allergy, renal insufficiency or drug reaction should be observed for several hours after drug administration.
- CAUTION SHOULD BE EXERCISED WHEN A CONTRAST ENHANCED INTERPRETATION IS MADE IN THE ABSENCE OF A COMPANION UNENHANCED MRI. Some paramagnetic contrast agents may impair the visualization of existing lesions seen on a non-contrast MRI.
- 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 safety of repeated doses has not been studied.
- Diagnostic procedures involving the use of MRI contrast agents should be conducted under supervision of a physician with the prerequisite training and a thorough knowledge of the procedure to be performed. Appropriate facilities should be available for coping with any complication of the procedure, as well as for emergency treatment of severe reactions to the contrast itself.

ADVERSE REACTIONS

- Serious adverse reactions include persistent paresthesia or numbness of unknown etiology. Post-marketing surveillance reports have identified cases of Nephrogenic Systemic Fibrosis (NSF); hypersensitivity reactions including bronchospasm and laryngeal/pharyngeal edema; and seizure.

USE IN SPECIFIC POPULATIONS

- Women should discontinue nursing and discard breast milk up to 72 hours after Optimark.
- The safety and effectiveness of Optimark Injection in pediatric patients has not been established. Pediatric patients may be particularly vulnerable to adverse GBCA reactions due to renal immaturity and/or unrecognized renal insufficiency.

Ordering Information

Description	Qty	Unit	Size	Order #	11 Digit NDC
Syringe, Ultraject™ prefilled	10	each	10 mL	117711	00019117710
Syringe, Ultraject™ prefilled	10	each	15 mL	117716	00019117715
Syringe, Ultraject™ prefilled	10	each	20 mL	117721	00019117720
Syringe, Ultraject™ prefilled	10	each	30 mL	117731	00019117730
Vial	10	each	5 mL	117702	00019117702
Vial	10	each	10 mL	117704	00019117704
Vial	10	each	15 mL	117706	00019117706
Vial	10	each	20 mL	117708	00019117708
Vial, multi-dose	5	each	50 mL	117750	00019117750