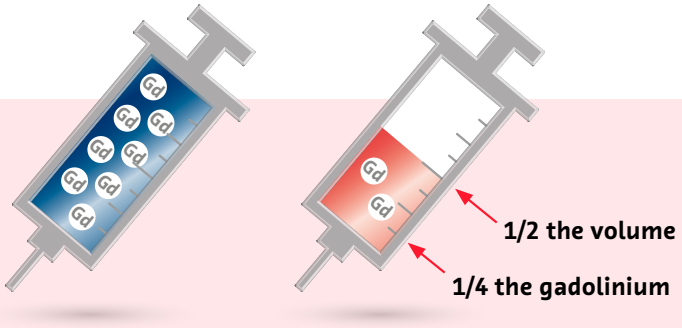
Dosing with Eovist® (gadoxetate disodium) Injection

Eovist is for intravenous administration. The recommended dose of Eovist is 0.1 mL/kg body weight (0.025 mmol/kg body weight).



0.5 Molar Extracellular GBCA | **0.25 Molar Eovist**

Indication and Usage

Eovist® (gadoxetate disodium) injection is indicated for intravenous use in magnetic resonance imaging (MRI) of the liver to detect and characterize lesions in patients with known or suspected focal liver disease.

Important Safety Information

WARNING: NEPHROGENIC SYSTEMIC FIBROSIS (NSF)

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.

- The risk for NSF appears highest among patients with:
  - Chronic, severe kidney disease (GFR <30 mL/min/1.73m^2), 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 (for example, age >60 years, hypertension or diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing.
- For patients at highest risk for NSF, do not exceed the recommended EOVIST dose and allow a sufficient period of time for eliminating of the drug from the body prior to any re-administration.

Please see additional Important Safety Information throughout this piece.

Please click here to see the Eovist® Full Prescribing Information.

Learn more about Eovist at eovist.com

Eovist®
(gadoxetate disodium) injection
0.25 mmol/mL

The dose of Eovist® (gadoxetate disodium) Injection is 0.025 mmol/kg

Dosage and Administration

Visually inspect Eovist® for particulate matter and discoloration prior to administration. Do not use the solution if it is discolored or if particulate matter is present. Eovist should not be mixed with other drugs. Eovist is intended for single use, and should be used immediately after opening. The rubber stopper should never be pierced more than once.

Administer Eovist undiluted as an intravenous bolus injection at a flow rate of approximately 2 mL/second. Flush the intravenous cannula with physiological saline solution after the injection. Discard any unused portion of an Eovist vial.

Body Weight		Total Volume (mL)
lb	**kg**	**0.25 Molar Eovist**
5.5	2.5	0.25
11	5	0.5
22	10	1
33	15	1.5
44	20	2
55	25	2.5
66	30	3
77	35	3.5
88	40	4
99	45	4.5
110	50	5
132	60	6
154	70	7
176	80	8
198	90	9
220	100	10
242	110	11
264	120	12
286	130	13
308	140	14

Important Safety Information (continued)

Contraindication and Important Information about Hypersensitivity Reactions: Eovist® is contraindicated in patients with history of severe hypersensitivity reactions to Eovist®. Anaphylactic and other hypersensitivity reactions with cardiovascular, respiratory and cutaneous manifestations, ranging from mild to severe, including shock have uncommonly occurred following Eovist® administration. Before Eovist® administration, assess all patients for any history of a reaction to contrast media, bronchial asthma and allergic disorders. These patients may have an increased risk for a hypersensitivity reaction to Eovist®.

Acute Kidney Injury: In patients with chronic renal impairment, acute kidney injury sometimes requiring dialysis has been observed with the use of some GBCAs. The risk of acute kidney injury might be lower with Eovist® due to its dual excretory pathways. Do not exceed the recommended dose; the risk of acute kidney injury may increase with higher than recommended doses.

Extravasation and Injection Site Reactions: Ensure catheter and venous patency before the injection of Eovist®. Extravasation into tissues during Eovist® administration may result in local tissue reactions. Strictly avoid intramuscular administration of Eovist® because it may cause myocyte necrosis and inflammation.

Please see additional Important Safety Information throughout this piece.

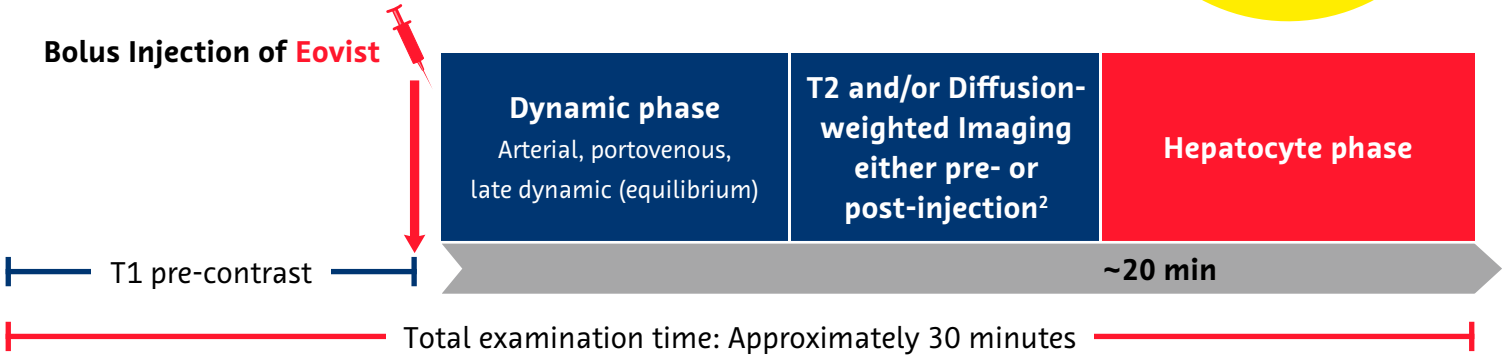
Please click here to see the Eovist® Full Prescribing Information.

Learn more about Eovist at eovist.com

Eovist®
(gadoxetate disodium) injection
0.25 mmol/mL

Magnetic Resonance Liver Imaging May Be Performed Within 30 Minutes

The Eovist® (gadoxetate disodium) injection dose of 0.025 mmol/kg is one quarter of the approved dose of other gadolinium-based contrast agents used in the liver.



- Hepatocyte imaging can be performed from approximately 20 minutes post-dose to approximately 120 minutes post-dose if needed
- Perform MR imaging no later than 60 minutes following Eovist administration to patients with elevated bilirubin or ferritin levels

Important Safety Information (continued)

Interference with Laboratory Tests: Serum iron determination using complexometric methods (for example, ferrocene complexation method) may result in falsely high or low values for up to 24 hours after the examination with Eovist® because of the caloxetate trisodium excipients.

Interference with Visualization of Liver Lesions: Severe renal or hepatic failure may impair Eovist® imaging performance. In patients with end-stage renal failure, hepatic contrast was markedly reduced and was attributed to elevated serum ferritin levels. In patients with abnormally high (>3 mg/dL) serum bilirubin, reduced hepatic contrast was observed. If Eovist® is used in these patients, complete MRI no later than 60 minutes after Eovist® administration and use a paired non-contrast and contrast MRI set for diagnosis.

Adverse Reactions: The most frequent (≥0.5%) adverse reactions associated with Eovist® are nausea (1.1%), headache (1.1%), feeling hot (0.8%), dizziness (0.6%), and back pain (0.6%).

Please see additional Important Safety Information throughout this piece.

Please click here to see the Eovist® Full Prescribing Information.

Learn more about Eovist at eovist.com

References: 1. Bluemke DA, Sahani D, Amendola M, et al. Efficacy and safety of MR imaging with liver-specific contrast agents: U.S. multicenter phase III study. *Radiology*. 2005;237(1):89-98. **2.** Zech CJ, Herrmann KA, Reiser MF, Schoenberg SO. MR imaging in patients with suspected liver metastases: value of liver-specific contrast agent Gd-EOB-DTPA. *Magn Reson Med Sci*. 2007;6:43-52. **3.** Data on file. Bayer HealthCare.

Bayer HealthCare

Radiology
Bayer HealthCare Medical Care
Bayer HealthCare LLC
100 Bayer Boulevard
P.O. Box 915
Whippany, NJ 07981
www.radiologysolutions.bayer.com

Bayer reserves the right to modify the specifications and features described herein, or discontinue manufacture of the product described at any time without prior notice or obligation. Please contact your authorized Bayer HealthCare representative for the most current information.

Bayer, the Bayer Cross, and Eovist® are trademarks of the Bayer group of companies.
© 2015 Bayer

PP-320-US-0068 October 2015