Eovist®
(gadoxetate disodium) injection
0.25 mmol/mL

Identifying Lesion Types With Eovist Injection

Focal Liver Lesion Signal Patterns

The characterization of focal liver lesions is based on many different criteria. The most important are:

- **In T1- and T2-weighted images:** signal intensity
- **In typical post-contrast perfusion phase images:** homogeneity, size, circumspection, shape, and necrosis

To explain some typical signal intensities of focal lesions, a schematic representation of the most frequent benign and malignant lesions in non-cirrhotic or cirrhotic liver parenchyma is given in the Signal Patterns charts on the following pages. Please note that the depicted lesions represent the typical (or most frequently observed) characteristics—like in a student teaching manual—but in clinical routine many more variations and borderline cases exist.

The last column of the tables depicts the typical behavior of focal liver lesions during the hepatocyte phase, approximately 20 minutes after injection of Eovist. While reading the tables, please pay particular attention to this column. The hepatocyte phase provides an additional important criterion for the characterization of focal lesions: information about liver-specific enhancement of focal lesions is hepatocyte-selective and correlates with various histopathologic diagnoses regarding presence of certain hepatocytic functions.[1]

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 SYSTEM 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.

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.

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

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Identifying Lesions in the Non-cirrhotic Liver With Eovist

	Focal Lesion	T2-weighted Image	T1-weighted Image			
			Pre-contrast[2-13]	Dynamic Image		
				Arterial Phase (approx. 20 seconds after injection)	Portovenous Phase (approx. 60 seconds after injection)	Late Dynamic Phase (2–3 minutes after injection)	Hepatocyte Phase (approx. 20 minutes after injection)
Malignant	Liver Metastases[1,2] (in case of hypovascular primary tumor)						
Benign	Hemangioma[2]*						
	Focal Nodular Hyperplasia[3,4]						
	Cyst[5]						
	Adenoma[1,4,6]						

* Small or high-flow hemangiomas (so-called flash filling) may appear uniformly hyperintense on the arterial and portovenous phase images. Remember that the signal intensity in all hemangioma always follows blood signal characteristics throughout all phases.

Please note: These are typical signal patterns of the lesions shown above. Some lesions may not enhance as depicted.

This chart is provided for reference only and is not intended to diagnose or treat any condition. Actual diagnoses and treatment decisions should be made based on professional judgment and additional clinical data, as may be deemed necessary by appropriately trained medical personnel.

Important Safety Information (continued)

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.

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.

Please see additional Important Safety Information throughout this piece.

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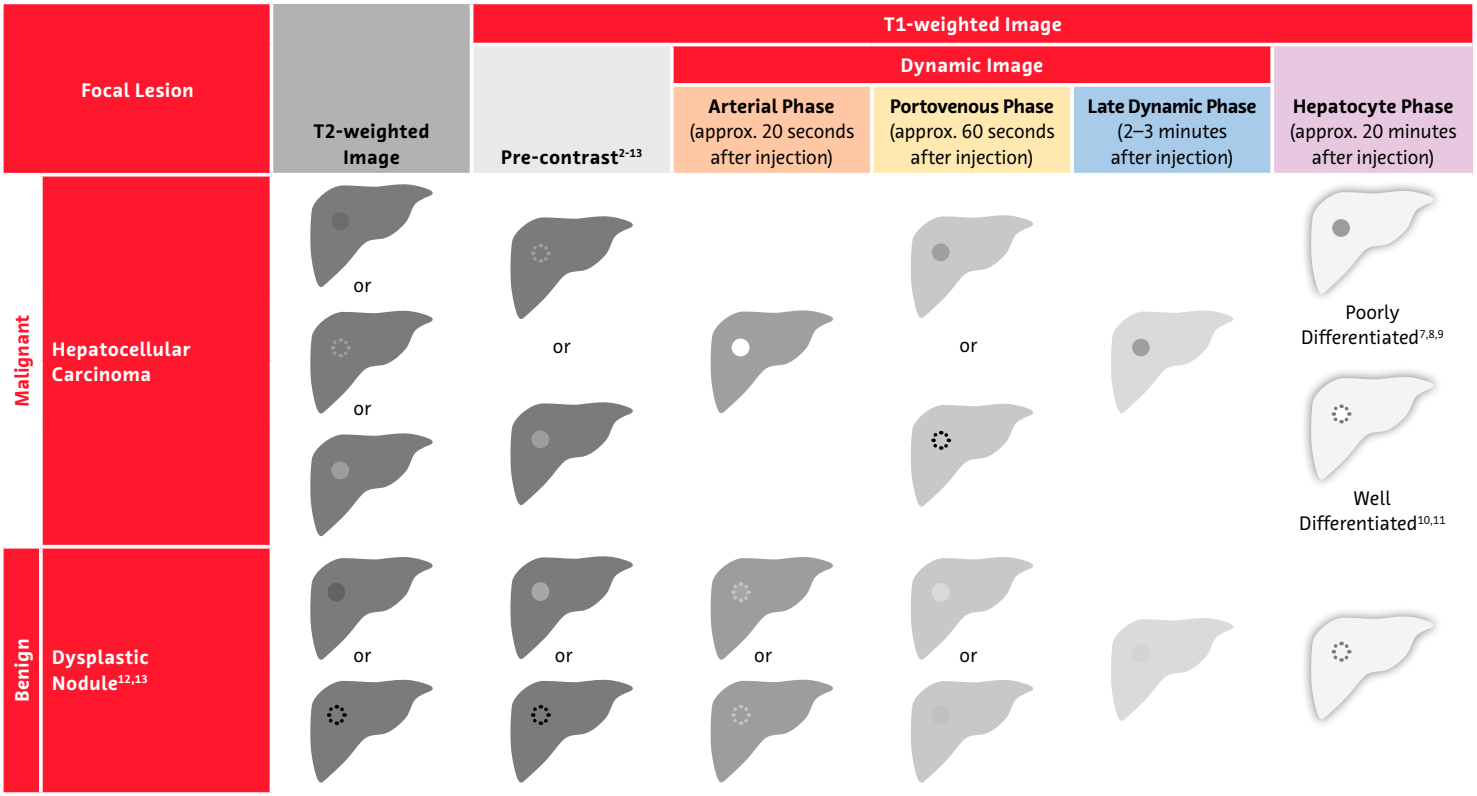
Identifying Lesions in the Cirrhotic Liver With Eovist



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Please note: These are typical signal patterns of the lesions shown above. Some lesions may not enhance as depicted.

This chart is provided for reference only and is not intended to diagnose or treat any condition. Actual diagnoses and treatment decisions should be made based on professional judgment and additional clinical data, as may be deemed necessary by appropriately trained medical personnel.

Important Safety Information (continued)

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%).

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References: **1.** Huppertz A, Haraida S, Kraus A, et al. Enhancement of focal liver lesions at gadoxetic acid-enhanced MR imaging: correlation with histopathologic findings and spiral CT—initial observations. *Radiology*. 2005;234(2):468-478. **2.** Motosugi U, Ichikawa T, Onohara K, et al. Distinguishing hepatic metastasis from hemangioma using gadoxetic acid-enhanced magnetic resonance imaging. *Invest Radiol*. 2011;46(6):359-365. **3.** Zech CJ, Grazioli L, Breuer J, Reiser MF, Schoenberg SO. Diagnostic performance and description of morphological features of focal nodular hyperplasia in Gd-EOB-DTPA-enhanced liver magnetic resonance imaging: results of a multicenter trial. *Invest Radiol*. 2008;43(7):504-511. **4.** Grazioli L, Bondioni MP, Haradome H, et al. Hepatocellular adenoma and focal nodular hyperplasia: value of gadoxetic acid-enhanced MR imaging in differential diagnosis. *Radiology*. 2012;262(2):520-529. **5.** Kim YK, Park G, Kim CS, Yu HC, Han YM. Diagnostic efficacy of gadoxetic acid-enhanced MRI for the detection and characterisation of liver metastases: comparison with multidetector-row CT. *Br J Radiol*. 2012;85(1013):539-547. **6.** Denecke T, Steffen IG, Agarwal S, et al. Appearance of hepatocellular adenomas on gadoxetic acid-enhanced MRI. *Eur Radiol*. 2012;22(8):1769-1775. **7.** Sano K, Ichikawa T, Motosugi U, et al. Imaging study of early hepatocellular carcinoma: usefulness of gadoxetic acid-enhanced MR imaging. *Radiology*. 2011;261(3):834-844. **8.** Park G, Kim YK, Kim CS, Yu HC, Hwang SB. Diagnostic efficacy of gadoxetic acid-enhanced MRI in the detection of hepatocellular carcinomas: comparison with gadopentetate dimeglumine. *Br J Radiol*. 2010;83(996):1010-1016. **9.** Ahn SS, Kim MJ, Lim JS, Hong HS, Chung YE, Choi JY. Added value of gadoxetic acid-enhanced hepatobiliary phase MR imaging in the diagnosis of hepatocellular carcinoma. *Radiology*. 2010;255(2):459-466. **10.** Tsuboyama T, Onishi H, Kim T, et al. Hepatocellular carcinoma: hepatocyte-selective enhancement at gadoxetic acid-enhanced MR imaging—correlation with expression of sinusoidal and canalicular transporters and bile accumulation. *Radiology*. 2010;255(3):824-833. **11.** Narita M, Hatano E, Arizono S, et al. Expression of OATP1B3 determines uptake of Gd-EOB-DTPA in hepatocellular carcinoma. *J Gastroenterol*. 2009;44(7):793-798. **12.** Chou CT, Chen YL, Wu HK, Chen RC. Characterization of hyperintense nodules on precontrast T1-weighted MRI: utility of gadoxetic acid-enhanced hepatocyte-phase imaging. *J Magn Reson Imaging*. 2011;33(3):625-632. **13.** Golfieri R, Grazioli L, Orlando E, et al. Which is the best MRI marker of malignancy for atypical cirrhotic nodules: hypointensity in hepatobiliary phase alone or combined with other features? Classification after Gd-EOB-DTPA administration. *J Magn Reson Imaging*. 2012;36(3):648-657.

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