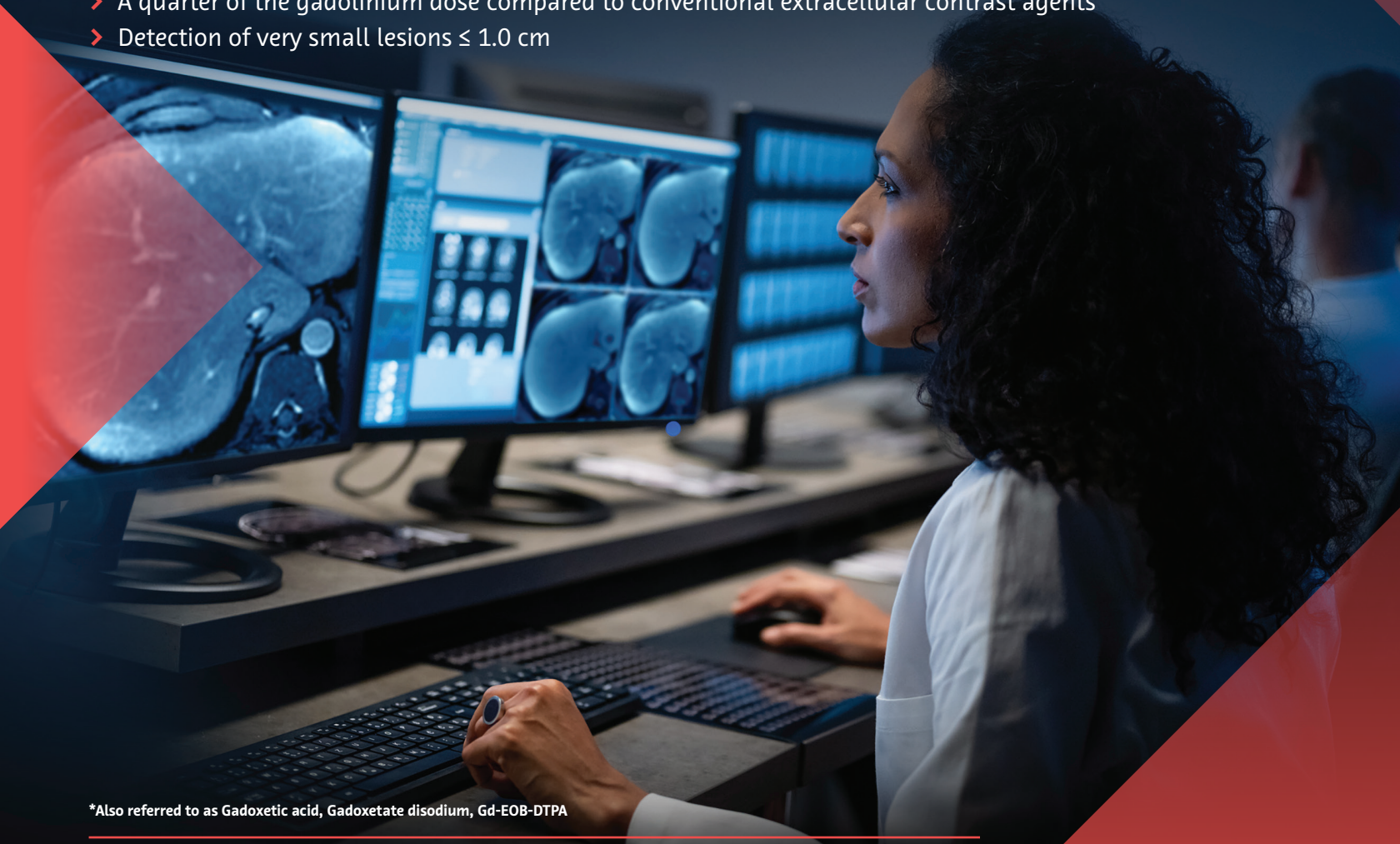
Primovist®

An Essential Diagnostic Tool to Support Your MR Liver Imaging Practice[1,8]

- Liver hepatocyte-specific properties
- Dual elimination pathway (50% hepatobiliary, 50% renal)
- Dynamic and delayed hepatobiliary phase imaging
- A quarter of the gadolinium dose compared to conventional extracellular contrast agents
- Detection of very small lesions ≤ 1.0 cm



*Also referred to as Gadoxetic acid, Gadoxetate disodium, Gd-EOB-DTPA

Important Safety Information

- PRIMOVIST (gadoxetate disodium injection) is a gadolinium-based contrast agent (GBCA) indicated for intravenous use in T1-weighted magnetic resonance imaging (MRI) of the liver to detect and characterize lesions in adults with known or suspected focal liver disease.
- Safety and effectiveness in pediatric patients have not been established.

Please see additional important Safety Information throughout this brochure.

Primovist®
Gadoxetic Acid

Primovist®: The Only Health Canada-Approved Hepatobiliary Specific Contrast Agent for MR Liver Imaging

It is a **bi-phasic contrast agent** combining **dynamic phase imaging** (similar to extracellular agents) **along with hepatobiliary phase information** to support your comprehensive evaluation of focal liver disease.[1]

Dynamic + Hepatobiliary Imaging = **Comprehensive Imaging**

Further assessment of lesions through hepatobiliary phase imaging:

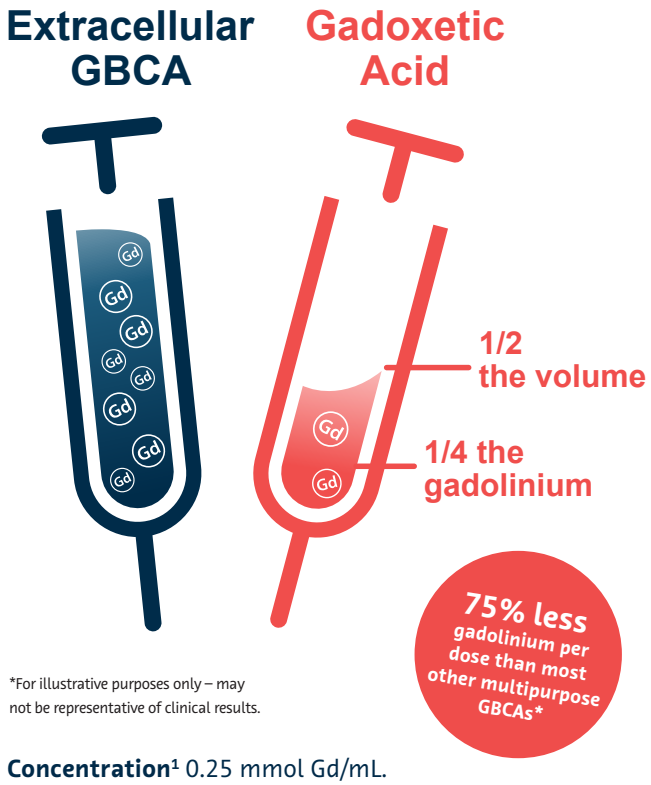
- Lesions with little or **no hepatocyte function** will generally not accumulate Primovist®
- Lesions with **normal hepatocyte function will accumulate Primovist**[1]

Most serious warnings and precautions:

- **Nephrogenic systemic fibrosis (NSF):** GBCAs increase the risk for NSF in patients with chronic severe renal insufficiency (glomerular filtration rate < 30 mL/min/1.73 m^2) or acute renal failure / acute kidney injury. In these patients, avoid use of GBCAs unless the diagnostic information is essential and not available with noncontrast-enhanced MRI. NSF may result in fatal or debilitating systemic fibrosis affecting the skin, muscle, and internal organs. Screen all patients for renal dysfunction by obtaining a history and/or laboratory tests. When administering a GBCA, do not exceed the recommended dose and allow a sufficient period of time for elimination of the agent from the body prior to any readministration.
- **Not for intrathecal use:** PRIMOVIST is not approved for intrathecal use. Intrathecal administration of GBCAs can cause serious, life-threatening, and fatal reactions, primarily with neurological reactions (e.g., coma, encephalopathy, seizures).

Please see additional Important Safety Information throughout this brochure.

Primovist® Dosing[1,2,3]



*For illustrative purposes only – may not be representative of clinical results.

Concentration[1] 0.25 mmol Gd/mL.
Dose[1] 0.025 mmol Gd/kg = 0.1mL/kg body weight.

What Makes Primovist Unique?[1,8]

- Liver hepatocyte-specific properties
- Dual elimination pathway (50% hepatobiliary, 50% renal)
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- A quarter of the gadolinium dose compared to conventional extracellular contrast agents
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Common Usage[2]

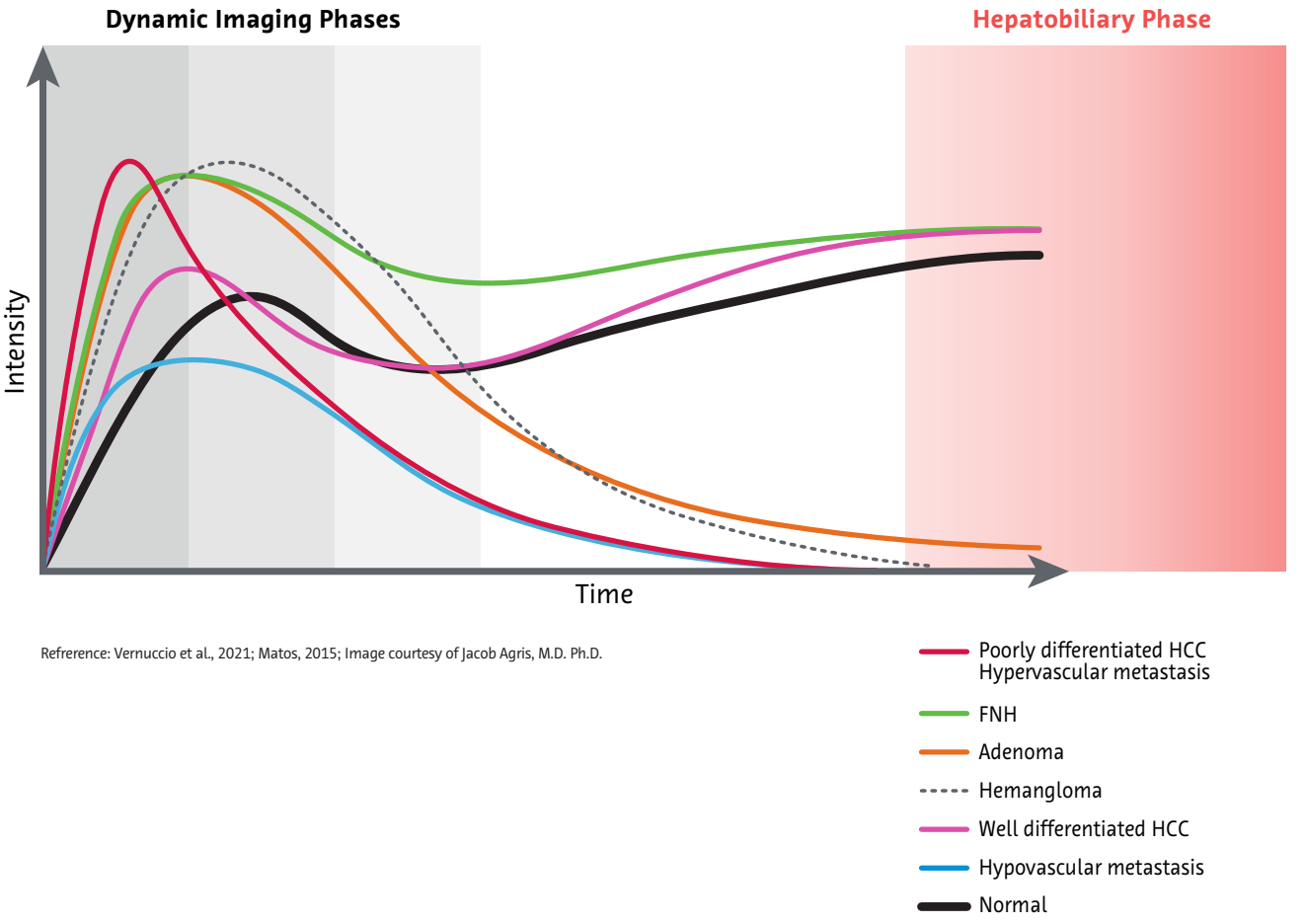
- Focal Nodular Hyperplasia
- Hepatic Adenoma
- Liver Metastases – particularly from colorectal or pancreatic cancer
- Hepatocellular Carcinoma

Other relevant warnings and precautions:

- Avoid intramuscular administration due to local intolerance reactions including focal necrosis
- Severe renal or hepatic failure may impair PRIMOVIST imaging performance
- Gadolinium may accumulate in the brain after multiple administrations of GBCAs. Use the lowest effective dose and perform a benefit risk assessment before administering repeated doses.
- Exercise caution when administering to patients with severe cardiovascular problems
- Hypersensitivity reactions including anaphylactoid reactions with cardiovascular, respiratory, and cutaneous manifestations, ranging from mild to severe reactions including shock have occurred very rarely following administration. Prior to administration assess all patients for a history of reaction to contrast media; bronchial asthma; allergic disorders. Administer only where trained personnel and therapies are promptly available for the treatment of hypersensitivity reactions.
- Use only during pregnancy if the clinical condition of the woman requires its use.

Please see additional Important Safety Information throughout this brochure.

Lesion Uptake Trends[4,5,9,10]



Refrerence: Vernuccio et al., 2021; Matos, 2015; Image courtesy of Jacob Agris, M.D. Ph.D.

Adverse reactions:

Most adverse drug reactions reported with PRIMOVIST were of mild to moderate severity, and did not require a discontinuation of the procedure. The most frequently reported adverse reactions in clinical trails were headache (0.6%; mild), nausea (0.7%; usually occurring just after injection and resolving quickly), and a feeling hot (0.7%; usually occurring during injection).

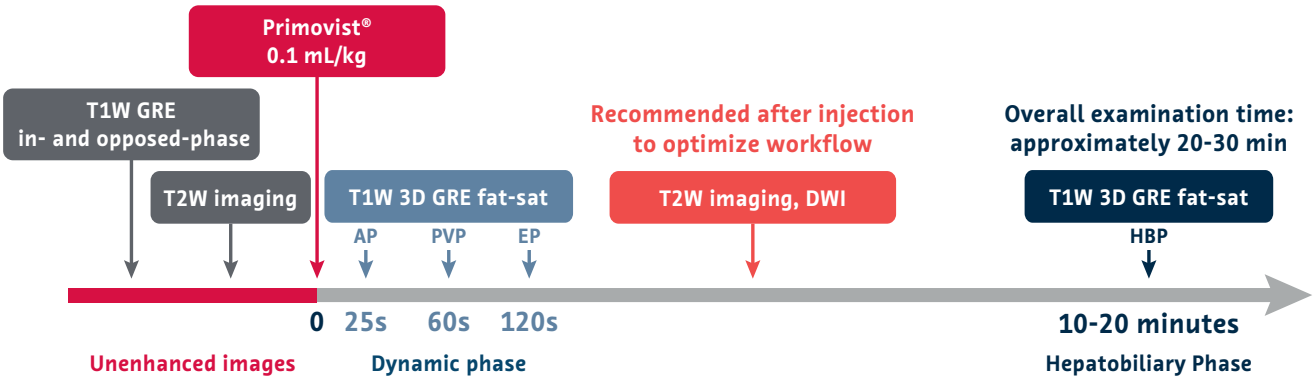
For more information:

Consult the product monograph https://www.bayer.com/sites/default/files/2020-11/primovist-pm-en.pdf for important information about for adverse reactions, interactions, and dosing. The Product Monograph is also available by calling Bayer Medical Information at 1-800-265-7382.

Please see additional Important Safety Information throughout this brochure.

Protocol optimization for hepatobiliary imaging with Primovist®[2,6]

Workflow optimization



GRE = gradient echo sequence, fat-sat = fat suppressed * T2-weighted imaging can be conducted before or after Primovist® administration. T2 MRCP should be acquired before contrast injection

Scan Time

- T2 and DWI imaging can be performed post-injection without compromising diagnostic capability
- While hepatocyte-phase imaging typically occurs at 20 minutes post injection, the diagnostic and technical efficacy results of two clinical studies suggest a minimal improvement at 20 minutes post injection over those at 10 minutes post Injection

Image Quality: Arterial Phase

- Consider your injection flow rate
- Use bolus detection method or multiple arterial phase image acquisition
- Adopt motion insensitive MR sequences or technology

Image Quality: Hepatobiliary Phase

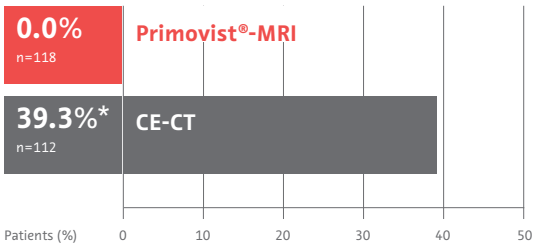
- Higher flip angles (20-35°) can be used for the 3D T1-weighted gradient-echo acquisition of the hepatobiliary phase

Decreased need for further imaging when using Primovist as initial imaging modality[7]

VALUE Study

Objective: To compare Primovist®-MRI with CE-CT for hepatic staging of patients with suspected CRCLM (colorectal cancer liver metastases)

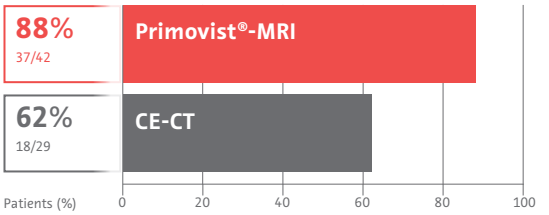
Patients requiring further imaging for diagnosis and therapy decisions



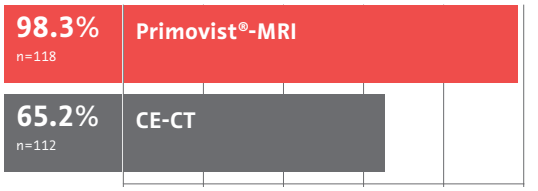
[a] Per-protocol set analysis. *
p<0.001

Percentage of patients requiring further imaging for diagnosis and therapy decision in patients that received either Primovist®-MRI or CECT as initial imaging modality.

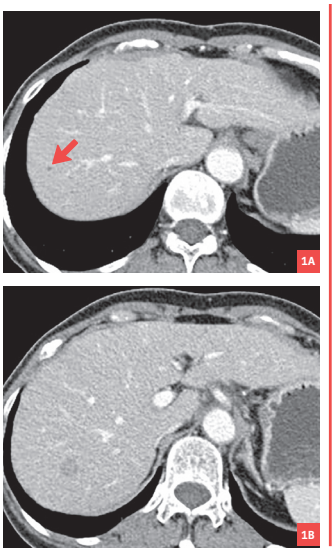
Percentage of patients with equal numbers of lesions at final diagnosis versus initial consensus



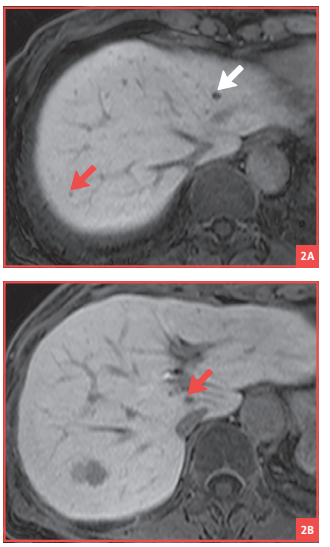
High and very high diagnostic confidence after initial imaging technique (rated by radiologists and surgeons)



Initial Imaging: CE-CT



Secondary Imaging: Primovist®-MRI



Study courtesy of the Department of Clinical Radiology, University of Munich Hospitals, Grosshardern Campus, Munich, Germany

Increased diagnostic accuracy with potential impacts on surgical planning[8]

Canadian Data

Objective: To compare Primovist®-MRI with CE-CT for hepatic staging of patients with suspected CRCLM (colorectal cancer liver metastases).

Compared to CE-CT, Primovist demonstrated:

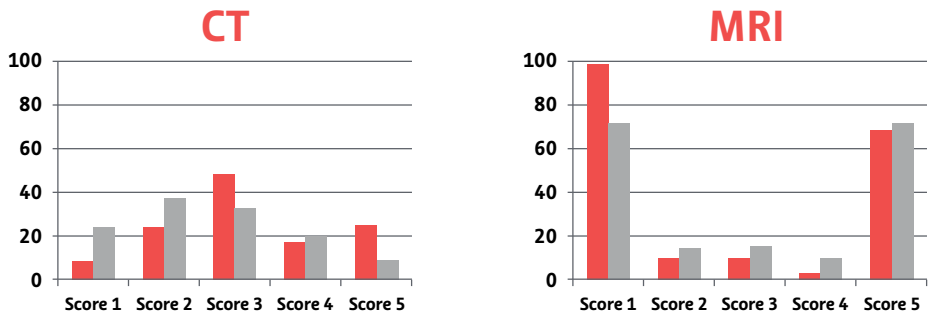
- Higher sensitivity in detecting CRCLM ≤ 1.0 cm
- Lower indeterminate lesion diagnosis
- Higher interobserver concordance in characterizing lesions

- Overall, Primovist®-enhanced MRI had a higher yield of detecting CRCLM at an organ, lobar, and/or segmental level – **which could have changed surgical planning in ~45% of patients**

Primovist® demonstrated lower amount of indeterminate lesion diagnosis compared to CECT.

Score 1: Definitely metastasis
Score 2: Probably metastasis
Score 3: Indeterminate
Score 4: Probably benign
Score 5: Definitely benign

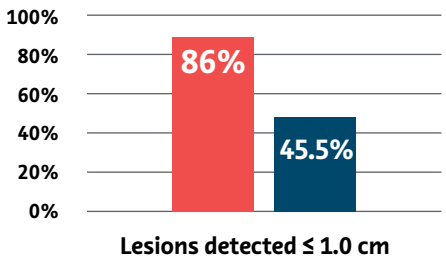
Reader 1 Reader 2



Sensitivity for detecting lesions

Primovist®-enhanced MRI

CECT



MRI detected additional metastases (41 and 38 lesions for reader 1 and 2) compared to CT.

References:

1. Primovist Product Monograph. June 14, 2024. Available at: https://health-products.canada.ca/dpd-bdpp/index-eng.jsp
2. Jhaveri et al. AJR Am J Roentgenol. 2015; 204(3):498-509.
3. Magnevist Product Monograph. June 14, 2024. Available at: https://health-products.canada.ca/dpd-bdpp/index-eng.jsp
4. Ringe et al. AJR Am J Roentgenol. 2010 Jul;195(1):13-28
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6. Huh et al. Korean J Radiol. 2015; 16(6), 1207-1215.
7. Zech et al. Br J Surg. 2014; 101(6):613-21
8. Jhaveri et al. HPB (Oxford). 2017 Nov;19(11):992-1000.
9. Matos, A. P. (2015). World Journal of Hepatology, 7(16), 1987.
10. Vernuccio, F.,et al (2021). Insights into Imaging, 12(1).

Other Bayer MRI Portfolio Solutions

Bayer has developed many advancements across the MRI spectrum. This well-recognized heritage allows us to understand the interdependencies between contrast, injectors, informatics and service to heighten our MRI offering and value to customers.

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Comprehensive Equipment Service and Solutions Delivery Support

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- The value Primovist can provide your site and your patient care
- Additional ways to optimizing your Primovist scan time and quality
- Plus additional resources: Bayer Radiology Academy

Speak to your Bayer Representative or contact us to learn more

RADIOLOGY ACADEMY
For more resources

Direct your patient to our patient website to reduce scan-xiety.

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