Bracco Diagnostics Inc.

Product HCPCS Codes

The individuals who appear are for illustrative purposes. All persons depicted are models and not real patients or healthcare professionals.

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HCPCS Coding & Reimbursement Guide

The Healthcare Common Procedure Coding System (HCPCS) information in the following tables can assist you in coding for Bracco Diagnostics' products and technologies. We at Bracco Diagnostics are committed to supporting all of our customers with resources to assist with coverage, coding, and reimbursement.

The source for all of the HCPCS codes featured in this booklet is the Centers for Medicare & Medicaid Services (CMS) NDC-HCPCS Crosswalk file. You may access this document at https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2021-asp-drug-pricing-files

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multihance® (gadobenate dimeglumine) injection, 529 mg/mL

TRUST EARNED

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MultiHance® Contrast Agent

HCPCS Codes	Product Description	CMS Product Abbreviations	Product SKU	NDC	Unit Size	HCPCS Dosage	HCPCS Billing Units
A9577	MultiHance® (gadobenate dimeglumine) Injection, 529 mg/mL	Inj. MultiHance	5164-12	0270-5164-12	5 x 5 mL vials/box	1mL	5
A9577	MultiHance® (gadobenate dimeglumine) Injection, 529 mg/mL	Inj. MultiHance	5164-13	0270-5164-13	5 x 10 mL vials/box	1mL	10
A9577	MultiHance® (gadobenate dimeglumine) Injection, 529 mg/mL	Inj. MultiHance	5164-14	0270-5164-14	5 x 15 mL vials/box	1mL	15
A9577	MultiHance® (gadobenate dimeglumine) Injection, 529 mg/mL	Inj. MultiHance	5164-15	0270-5164-15	5 x 20 mL vials/box	1mL	20

MultiHance® Multipack™ Contrast Agent

HCPCS Codes	Product Description	CMS Product Abbreviations	Product SKU	NDC	Unit Size	HCPCS Dosage	HCPCS Billing Units
A9578	MultiHance® Multipack™ (gadobenate dimeglumine) Injection, 529 mg/mL	Inj. MultiHance Multipack	5264-16	0270-5164-16	5 x 50 mL bottles/box	1mL	50
A9578	MultiHance® Multipack™ (gadobenate dimeglumine) Injection, 529 mg/mL	Inj. MultiHance Multipack	5264-17	0270-5164-17	5 x 100 mL bottles/box	1mL	100

ProHance®
(Gadoteridol) Injection, 279.3 mg/mL
STABILITY. SAFETY. EFFICACY.

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ProHance® Contrast Agent

HCPCS Codes	Product Description	CMS Product Abbreviations	Product SKU	NDC	Unit Size	HCPCS Dosage	HCPCS Billing Units
A9579	ProHance® (Gadoteridol) Injection, 279.3 mg/mL	Gad-base MR Contrast NOS, 1mL	1111-04	0270-1111-04	5 x 5 mL vials/box	1mL	5
A9579	ProHance® (Gadoteridol) Injection, 279.3 mg/mL	Gad-base MR Contrast NOS, 1mL	1111-01	0270-1111-01	5 x 10 mL vials/box	1mL	10
A9579	ProHance® (Gadoteridol) Injection, 279.3 mg/mL	Gad-base MR Contrast NOS, 1mL	1111-02	0270-1111-02	5 x 15 mL vials/box	1mL	15
A9579	ProHance® (Gadoteridol) Injection, 279.3 mg/mL	Gad-base MR Contrast NOS, 1mL	1111-03	0270-1111-03	5 x 20 mL vials/box	1mL	20

ProHance® Multipack™ Contrast Agent

HCPCS Codes	Product Description	CMS Product Abbreviations	Product SKU	NDC	Unit Size	HCPCS Dosage	HCPCS Billing Units
A9576	ProHance® Multipack™ (Gadoteridol) Injection, 279.3 mg/mL	Inj. MultiHance Multipack	1111-70	0270-1111-70	5 x 50 mL bottles/box	1mL	50

ISOVUE®
(iopamidol injection)

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ISOVUE®-200 Contrast Agent, ISOVUE®-250 Contrast Agent

HCPCS Codes	Product Description	CMS Product Abbreviations	Product SKU	NDC	Unit Size	HCPCS Dosage	HCPCS Billing Units
Q9966	ISOVUE®-200 (iopamidol injection 41%)	LOCM 200-299mb/mL iodine, 1 mL	1314-15	0270-1314-15	5 x 200 mL vials/case	1mL	200
Q9966	ISOVUE®-250 (iopamidol injection 51%)	LOCM 200-299mb/mL iodine, 1 mL	1317-02	0270-1317-02	10 x 100 mL bottles/case	1mL	100

ISOVUE®
(iopamidol injection)

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ISOVUE®-300 Contrast Agent

HCPCS Codes	Product Description	CMS Product Abbreviations	Product SKU	NDC	Unit Size	HCPCS Dosage	HCPCS Billing Units
Q9967	ISOVUE®-300 (iopamidol injection 61%)	LOCM 300-399mb/mL iodine, 1 mL	1315-25	0270-1315-25	10 x 30 mL vials/case	1mL	30
Q9967	ISOVUE®-300 (iopamidol injection 61%)	LOCM 300-399mb/mL iodine, 1 mL	1315-30	0270-1315-30	10 x 50 mL vials /case	1mL	50
Q9967	ISOVUE®-300 (iopamidol injection 61%)	LOCM 300-399mb/mL iodine, 1 mL	1315-35	0270-1315-35	10 x 100 mL bottles /case	1mL	100
Q9967	ISOVUE®-300 (iopamidol injection 61%)	LOCM 300-399mb/mL iodine, 1 mL	1315-50	0270-1315-50	10 x 150 mL bottles/case	1mL	150

ISOVUE®-300 Imaging Bulk Package Contrast Agent

HCPCS Codes	Product Description	CMS Product Abbreviations	Product SKU	NDC	Unit Size	HCPCS Dosage	HCPCS Billing Units
Q9967	ISOVUE®-300 (iopamidol injection 61%) Imaging Bulk Package	LOCM 300-399mb/mL iodine, 1 mL	1315-45	0270-1315-45	10 x 200 mL bottles/case	1mL	200
Q9967	ISOVUE®-300 (iopamidol injection 61%) Imaging Bulk Package	LOCM 300-399mb/mL iodine, 1 mL	1315-95	0270-1315-95	6 x 500 mL bottles/case	1mL	500

ISOVUE® (iopamidol injection)

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ISOVUE®-370 Contrast Agent

HCPCS Codes	Product Description	CMS Product Abbreviations	Product SKU	NDC	Unit Size	HCPCS Dosage	HCPCS Billing Units
Q9967	ISOVUE®-370 (iopamidol injection 76%)	LOCM 300-399mb/mL iodine, 1 mL	1316-30	0270-1316-30	10 x 50 mL vials/case	1mL	50
Q9967	ISOVUE®-370 (iopamidol injection 76%)	LOCM 300-399mb/mL iodine, 1 mL	1316-52	0270-1316-52	10 x 75 mL bottles/case	1mL	75
Q9967	ISOVUE®-370 (iopamidol injection 76%)	LOCM 300-399mb/mL iodine, 1 mL	1316-35	0270-1316-25	10 x 100 mL bottles/case	1mL	100
Q9967	ISOVUE®-370 (iopamidol injection 76%)	LOCM 300-399mb/mL iodine, 1 mL	1316-04	0270-1316-04	10 x 125 mL bottles/case	1mL	125
Q9967	ISOVUE®-370 (iopamidol injection 76%)	LOCM 300-399mb/mL iodine, 1 mL	1316-37	0270-1316-37	10 x 150 mL bottles/case	1mL	150

ISOVUE®-370 Imaging Bulk Package Contrast Agent

HCPCS Codes	Product Description	CMS Product Abbreviations	Product SKU	NDC	Unit Size	HCPCS Dosage	HCPCS Billing Units
Q9967	ISOVUE®-370 (iopamidol injection 76%) Imaging Bulk Package	LOCM 300-399mb/mL iodine, 1 mL	1316-45	0270-1316-45	10 x 200 mL bottles/case	1mL	200
Q9967	ISOVUE®-370 (iopamidol injection 76%) Imaging Bulk Package	LOCM 300-399mb/mL iodine, 1 mL	1316-95	0270-1316-95	6 x 500 mL bottles/case	1mL	500

ISOVUE-M®
(iopamidol injection)

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ISOVUE-M® 200 Contrast Agent, ISOVUE-M® 300 Contrast Agent

HCPCS Codes	Product Description	CMS Product Abbreviations	Product SKU	NDC	Unit Size	HCPCS Dosage	HCPCS Billing Units
Q9966	ISOVUE-M® 200 (iopamidol injection 41%)	LOCM 200-299mb/mL iodine, 1 mL	1411-11	0270-1411-11	10 x 10 mL vials/box	1mL	10
Q9966	ISOVUE-M® 200 (iopamidol injection 41%)	LOCM 200-299mb/mL iodine, 1 mL	1411-25	0270-1411-25	10 x 20 mL vials/box	1mL	20
Q9967	ISOVUE-M® 300 (iopamidol injection 61%)	LOCM 300-399mb/mL iodine, 1 mL	1412-15	0270-1412-15	10 x 15 mL vials/box	1mL	15

CYSTOGRAFIN®
(diatrizoate meglumine injection USP 30%)

CYSTOGRAFIN®-DILUTE
(diatrizoate meglumine injection USP 18%)

Please see indications, important safety information, and links to full prescribing information at the end of this document.

HCPCS Codes	Product Description	CMS Product Abbreviations	Product SKU	NDC	Unit Size	HCPCS Dosage	HCPCS Billing Units
Q9958	CYSTOGRAFIN® (diatrizoate meglumine Injection USP 30%)	HOCM<=149mg/ml iodine, 1 mL	0149-60	0270-0149-60	10 x 100mL bottles/case	1mL	100
Q9958	CYSTOGRAFIN® (diatrizoate meglumine Injection USP 30%)	HOCM<=149mg/ml iodine, 1 mL	0149-57	0270-0149-57	10 x 300 mL bottles/case	1mL	300
Q9958	CYSTOGRAFIN®-Dilute (diatrizoate meglumine Injection USP 18%)	HOCM<=149mg/ml iodine, 1 mL	0149-30	0270-1410-30	10 x 300 mL bottles/case	1mL	300

GASTROGRAFIN®
(diatrizoate meglumine and diatrizoate sodium solution USP)

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HCPCS Codes	Product Description	CMS Product Abbreviations	Product SKU	NDC	Unit Size	HCPCS Dosage	HCPCS Billing Units
Q9963	GASTROGRAFIN® (diatrizoate meglumine and diatrizoate sodium solution USP)	HOCM <= 149mg/ml iodine, 1 mL	0445-35	0270-0445-35	24 x 30 mL bottles/case	1mL	30
Q9963	GASTROGRAFIN® (diatrizoate meglumine and diatrizoate sodium solution USP)	HOCM <= 149mg/ml iodine, 1 mL	0445-40	0270-0445-40	12 x 120 mL bottles/case	1mL	120

LUMASON®
(sulfur hexafluoride lipid-type A microspheres)
for injectable suspension, for intravenous use or intravesical use

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HCPCS Codes	Product Description	CMS Product Abbreviations	Product SKU	NDC	Unit Size	HCPCS Dosage	HCPCS Billing Units Per Vial
Q9950	LUMASON® (sulfur hexafluoride lipid-type A microspheres) for injectable suspension, for intravenous use or intravesical use	Inj sulf hexa lipid microsph	7099-16	0270-7099-16	5 x 5 mL vials per box	1mL	5
Q9950	LUMASON® (sulfur hexafluoride lipid-type A microspheres) for injectable suspension, for intravenous use or intravesical use	Inj sulf hexa lipid microsph	7099-07	0270-7099-07	20 x 5 mL vials per box	1mL	5

Cardiogen-82™
(Rubidium Rb 82 Generator)

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HCPCS Codes	Product Description	CMS Product Abbreviations	Product SKU	NDC	HCPCS Dosage
A9555	CARDIOGEN-82® (Rubidium Rb 82 Generator)	Rubidium Rb-82	0091-01	0270-0091-01	Per study dose, up to 60 mCi

Kinevac®
Sincalide for Injection

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HCPCS Codes	Product Description	CMS Product Abbreviations	Product SKU	NDC	Unit Size	HCPCS Billing Units
J2805	Kinevac® (sincalide for injection)	Sincalide Inj	0556-15	0270-0556-15	10 x 5mcg vials/box	5

Varibar® (barium sulfate)

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VARIBAR® (barium sulfate), like all other barium contrast agents, does not have Level II HCPCS codes. Under Medicare, barium products are considered to be drugs used as supplies[1] and are not separately billable or paid. Hospitals should follow CMS' guidance for billing drugs that are packaged and paid as supplies, reporting coded and uncoded drugs with their charges under the revenue code associated with the cost center under which the hospital accumulates the costs for the drugs.

Check with your chargemaster specialist—common revenue codes for barium contrast agents are[2]:

- **0255:** drugs incident to radiology
- **0270:** medical/surgical supplies—general or
- **0621:** medical/surgical supplies—extension of 027X—incident to radiology

Commercial payors may or may not reimburse for barium products separately. Please check with your individual payor's plans.

For more information on our barium products, please see the complete Barium Contrast and Medical Accessories Catalog at https://imaging.bracco.com/us-en/products/fluoroscopy

1. Medicare Benefit Policy Manual, Chapter 15—Covered Medical and Other Health Services, Section 50.2.M
2. Hospital Revenue Codes, Noridian https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes—accessed May 25, 2021.

Important Safety Information

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MultiHance® (gadobenate dimeglumine) injection, 529 mg/mL
and
MultiHance® Multipack™ (gadobenate dimeglumine) injection, 529 mg/mL

Indications and Usage:

MultiHance® (gadobenate dimeglumine) injection, 529 mg/mL is a gadolinium-based contrast agent indicated for intravenous use in:

- Magnetic resonance imaging (MRI) of the central nervous system (CNS) in adults and pediatric patients (including term neonates) to visualize lesions with abnormal blood-brain barrier or abnormal vascularity of the brain, spine, and associated tissues and
- Magnetic resonance angiography (MRA) to evaluate adults with known or suspected renal or aorto-ilio-femoral occlusive vascular disease

IMPORTANT SAFETY INFORMATION:

WARNING: NEPHROGENIC SYSTEMIC FIBROSIS

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 systemic 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 (e.g. 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 MultiHance dose and allow a sufficient period of time for elimination of the drug from the body prior to re-administration.**

CONTRAINDICATIONS

MultiHance is contraindicated in patients with known allergic or hypersensitivity reactions to gadolinium-based contrast agents.

WARNINGS AND PRECAUTIONS

Nephrogenic Systemic Fibrosis: NSF has occurred in patients with impaired elimination of GBCAs. Higher than recommended dosing or repeated dosing appears to increase risk.

Hypersensitivity Reactions: Anaphylactic and anaphylactoid reactions have been reported, involving cardiovascular, respiratory, and/or cutaneous manifestations. Some patients experienced circulatory collapse and died. In most cases, initial symptoms occurred within minutes of MultiHance administration and resolved with prompt emergency treatment. Consider the risk for hypersensitivity reactions, especially in patients with a history of hypersensitivity reactions or a history of asthma or other allergic disorders.

Gadolinium Retention: Gadolinium is retained for months or years in several organs. The highest concentrations have been identified in the bone, followed by brain, skin, kidney, liver, and spleen. At equivalent doses, retention varies among the linear agents. Retention is lowest and similar among the macrocyclic GBCAs. Consequences of gadolinium retention in the brain have not been established, but they have been established in the skin and other organs in patients with impaired renal function. Minimize repetitive GBCA imaging studies, particularly closely spaced studies when possible.

Acute Renal Failure: In patients with renal insufficiency, acute renal failure requiring dialysis or worsening renal function have occurred with the use of GBCAs. The risk of renal failure may increase with increasing dose of the contrast agent. Screen all patients for renal dysfunction by obtaining a history and/or laboratory tests.

Extravasation and Injection Site Reactions: Extravasation of MultiHance may lead to injection site reactions, characterized by local pain or burning sensation, swelling, blistering, and necrosis. Exercise caution to avoid local extravasation during intravenous administration of MultiHance.

Cardiac Arrhythmias: Cardiac arrhythmias have been observed in patients receiving MultiHance in clinical trials. Assess patients for underlying conditions or medications that predispose to arrhythmias. The effects on QTc by MultiHance dose, other drugs, and medical conditions were not systematically studied.

Interference with Visualization of Certain Lesions: Certain lesions seen on non-contrast images may not be seen on contrast images. Exercise caution when interpreting contrast MR images in the absence of companion non-contrast MR images.

ADVERSE REACTIONS

The most commonly reported adverse reactions are nausea (1.3%) and headache (1.2%).

USE IN SPECIFIC POPULATIONS

Pregnancy: GBCAs cross the human placenta and result in fetal exposure and gadolinium retention. Use only if imaging is essential during pregnancy and cannot be delayed.

Lactation: There is no information on the effects of the drug on the breastfed infant or the effects of the drug on milk production. However, limited literature reports that breastfeeding after MultiHance administration to the mother would result in the infant receiving an oral dose of 0.001%-0.04% of the maternal dose.

Pediatric Use: MultiHance is approved for intravenous use for MRI of the CNS to visualize lesions with abnormal blood brain barrier or abnormal vascularity of the brain, spine, and associated tissues in pediatric patients from birth, including term neonates, to less than 17 years of age. Adverse reactions in pediatric patients were similar to those reported in adults. No dose adjustment according to age is necessary in pediatric patients two years of age and older. For pediatric patients, less than 2 years of age, the recommended dosage range is 0.1 to 0.2 mL/kg. The safety of MultiHance has not been established in preterm neonates.

Please see full Prescribing Information and Patient Medication Guide for additional important safety information for/regarding MultiHance (gadobenate dimeglumine) injection, 529 mg/mL at https://www.braccoimaging.com/us-en/products/magnetic-resonance-imaging/multihance

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

MultiHance is manufactured for Bracco Diagnostics Inc. by BIPSO GmbH – 78224 Singen (Germany) and by Patheon Italia S.p.A., Ferentino, Italy.

ProHance® (Gadoteridol) Injection, 279.3 mg/mL
and
ProHance® Multipack™ (Gadoteridol) Injection, 279.3 mg/mL

Indications and Usage:

CENTRAL NERVOUS SYSTEM

ProHance® (Gadoteridol) Injection, 279.3 mg/mL is indicated for use in MRI in adults and pediatric patients including term neonates to visualize lesions with disrupted blood brain barrier and/or abnormal vascularity in the brain (intracranial lesions), spine and associated tissues.

EXTRACRANIAL/EXTRASPINAL HEAD AND NECK

ProHance (Gadoteridol) Injection, 279.3 mg/mL is indicated for use in MRI in adults to visualize lesions in the head and neck.

IMPORTANT SAFETY INFORMATION:

WARNING: NEPHROGENIC SYSTEMIC FIBROSIS

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 systemic 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 (e.g. 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 ProHance dose and allow a sufficient period of time for elimination of the drug from the body prior to re-administration.**

CONTRAINDICATIONS

Contraindicated in patients with known allergic or hypersensitivity reactions to ProHance.

WARNINGS AND PRECAUTIONS

Nephrogenic Systemic Fibrosis: NSF has occurred in patients with impaired elimination of GBCAs. Higher than recommended dosing or repeated dosing appears to increase risk.

Hypersensitivity Reactions: Anaphylactic and anaphylactoid reactions have been reported, involving cardiovascular, respiratory, and/or cutaneous manifestations. Some patients experienced circulatory collapse and died. In most cases, initial symptoms occurred within minutes of administration and resolved with prompt emergency treatment. Prior to ProHance administration, ensure the availability of trained personnel and medications to treat hypersensitivity reactions. Consider these risks, especially in patients with a history of hypersensitivity reactions or a history of asthma or other allergic disorders.

Gadolinium Retention: Gadolinium is retained for months or years in several organs. The highest concentrations have been identified in the bone, followed by brain, skin, kidney, liver, and spleen. Linear GBCAs cause more retention than macrocyclic GBCAs. Consequences of gadolinium retention in the brain have not been established, but they have been established in the skin and other organs in patients with impaired renal function.

Acute Kidney Injury: In patients with chronically reduced renal function, acute kidney injury requiring dialysis has occurred with the use of GBCAs. The risk of acute kidney injury may increase with increasing dose of the contrast agent; administer the lowest dose necessary for adequate imaging.

ADVERSE REACTIONS

The most commonly reported adverse reactions are nausea and taste perversion with an incidence ≥ 0.9%.

USE IN SPECIFIC POPULATIONS

Pregnancy: GBCAs cross the human placenta and result in fetal exposure and gadolinium retention. Use only if imaging is essential during pregnancy and cannot be delayed.

Lactation: There are no data on the presence in human milk, the effects on the breastfed infant, or the effects on milk production. However, published lactation data on other GBCAs indicate that 0.01 to 0.04% of the maternal gadolinium dose is present in breast milk.

Pediatric Use: The safety and effectiveness of ProHance have been established for use with MRI to visualize lesions with abnormal blood brain barrier or abnormal vascularity of the brain, spine, and associated tissues in pediatric patients from birth, including term neonates, to 17 years of age. Adverse reactions in pediatric patients were similar to those reported in adults. No case of NSF associated with ProHance or any other GBCA has been identified in pediatric patients ages 6 years and younger.

Please see full Prescribing Information and Patient Medication Guide for additional important safety information for/regarding ProHance (Gadoteridol) Injection, 279.3 mg/mL at https://imaging.bracco.com/us-en/products/magnetic-resonance-imaging/prohance

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

ProHance is manufactured for Bracco Diagnostics Inc. by BIPSO GmbH – 78224 Singen (Germany).

Indications and Usage for ISOVUE® (Iopamidol Injection) ISOVUE®-200, 250, 300, 370

ISOVUE® (Iopamidol Injection) is indicated for angiography throughout the cardiovascular system in adults, including cerebral and peripheral arteriography, coronary arteriography and ventriculography, selective visceral arteriography and aortography, peripheral venography (phlebography), and in pediatric patients for angiocardiography; or for adult and pediatric intravenous excretory urography and intravenous adult and pediatric contrast enhancement of computed tomographic (CECT) head and body imaging.

Indications and Usage for ISOVUE®-300 (Iopamidol Injection 61%) Imaging Bulk Package* and ISOVUE®-370 (Iopamidol Injection 76%) Imaging Bulk Package*

ISOVUE® (Iopamidol Injection) Imaging Bulk Package (IBP) is indicated for angiography throughout the cardiovascular system in adults, including cerebral and peripheral arteriography, coronary arteriography and ventriculography, selective visceral arteriography and aortography, peripheral venography (phlebography), and in pediatric patients for angiocardiography; or for intravenous contrast enhancement of computed tomographic (CECT) imaging of the head and body in adult and pediatric patients.

*The ISOVUE (Iopamidol Injection) Imaging Bulk Package is for use with an automated contrast injector or a contrast management system approved or cleared for use with it.

IMPORTANT SAFETY INFORMATION:

ISOVUE (Iopamidol Injection) IS NOT FOR INTRATHECAL USE. Iopamidol Injection is available as ISOVUE-M 200 (Iopamidol Injection 41%), and ISOVUE-M 300 (Iopamidol Injection 61%) for intrathecal administration.

Nonionic iodinated contrast media inhibit blood coagulation, in vitro, less than ionic contrast media. Clotting has been reported when blood remains in contact with syringes containing nonionic contrast media. Serious, rarely fatal, thromboembolic events causing myocardial infarction and stroke have been reported during angiographic procedures with both ionic and nonionic contrast media. Therefore, meticulous intravascular administration technique is necessary, particularly during angiographic procedures, to minimize thromboembolic events.

Caution must be exercised in patients with severely impaired renal function, those with combined renal and hepatic disease, or anuria, particularly when larger and repeat doses are administered. Radiopaque diagnostic contrast agents are potentially hazardous in patients with multiple myeloma or other paraproteinemia, particularly in those with therapeutically resistant anuria. Caution should be exercised in hydrating patients with underlying conditions that may be worsened by fluid overload, such as congestive heart failure. Diabetic nephropathy may predispose to acute renal impairment following intravascular contrast media administration. Acute renal impairment following contrast media administration may precipitate lactic acidosis in patients who are taking biguanides. Preparatory dehydration is dangerous and may contribute to acute renal failure in patients with advanced vascular disease, diabetic patients, and in susceptible nondiabetic patients (often elderly with preexisting renal disease). Patients should be well hydrated prior to and following iopamidol administration.

The possibility of a reaction, including serious, life-threatening, fatal, anaphylactoid or cardiovascular reactions, should always be considered. Patients at increased risk include those with a history of a previous reaction to a contrast medium, patients with a known sensitivity to iodine per se, and patients with a known clinical hypersensitivity (bronchial asthma, hay fever, and food allergies). Severe cutaneous adverse reactions (SCAR) may develop from 1 hour to several weeks after intravascular contrast agent administration.

Please see full Prescribing Information for ISOVUE (Iopamidol Injection).

https://imaging.bracco.com/us-en/products/ct-ct-colonography/isovue

Please see full Prescribing Information for ISOVUE Imaging Bulk Package products.

https://imaging.bracco.com/us-en/products/ct-ct-colonography/isovue

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

ISOVUE and ISOVUE-M are currently manufactured for Bracco Diagnostics Inc. at three locations: BIPSO GmbH, Singen (Germany), Patheon Italia S.p.A., Ferentino (Italy) and S. M. Farmaceutici SRL, Tito (Italy).

ISOVUE-M® 200 (Iopamidol Injection 41%)
ISOVUE-M® 300 (Iopamidol Injection 61%)

Indications and Usage for ISOVUE-M® 200 (Iopamidol Injection 41%), ISOVUE-M® 300 (Iopamidol Injection 61%)

ISOVUE-M® (Iopamidol Injection) is indicated for intrathecal administration in adult neuroradiology including myelography (lumbar, thoracic, cervical, total columnar), and for contrast enhancement of computed tomographic (CECT) cisternography and ventriculography. ISOVUE-M 200 (Iopamidol injection 41%) is indicated for thoraco-lumbar myelography in children over the age of two years.

IMPORTANT SAFETY INFORMATION:

The need for myelographic examination should be carefully evaluated. Iopamidol should be administered with caution in patients with increased intracranial pressure or suspicion of intracranial tumor, abscess or hematoma, those with a history of convulsive disorder, severe cardiovascular disease, chronic alcoholism, or multiple sclerosis, and elderly patients. Particular attention must be given to state of hydration, concentration of medium, dose, and technique used in these patients.

Intrathecal administration of corticosteroids with iopamidol is contraindicated. Because of overdosage considerations, immediate repeat myelography in the event of technical failure is contraindicated. Myelography should not be performed in the presence of significant local or systemic infection where bacteremia is likely.

As with all injectable contrast agents, the possibility of severe reactions should be borne in mind, regardless of the patient's pre-existing medical history. As with any other iodinated contrast media, caution must be exercised in patients with severely impaired renal function, combined renal and hepatic disease, combined renal and cardiac disease, severe thyrotoxicosis, myelomatosis, or anuria, particularly when large doses are administered. Severe cutaneous adverse reactions (SCAR) may develop from 1 hour to several weeks after intravascular contrast agent administration.

Please see full Prescribing Information for ISOVUE-M products at https://imaging.bracco.com/us-en/products/myelography/isovue-m

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

ISOVUE-M is currently manufactured for Bracco Diagnostics Inc. at three locations: BIPSO GmbH, Singen (Germany), Patheon Italia S.p.A., Ferentino (Italy) and S. M. Farmaceutici SRL, Tito (Italy).

CYSTOGRAFIN® (diatrizoate meglumine injection USP 30%)
and
CYSTOGRAFIN®-Dilute (diatrizoate meglumine injection USP 18%)

Indications and Usage:

CYSTOGRAFIN® (diatrizoate meglumine injection USP 30%) and CYSTOGRAFIN®-Dilute (diatrizoate meglumine injection USP 18%) and are indicated for retrograde cystourethrography and are not intended for intravascular injection.

IMPORTANT SAFETY INFORMATION:

Severe sensitivity reactions are more likely to occur in patients with a history of bronchial asthma, significant allergies, or previous reactions to contrast agents.

A history of sensitivity to iodine per se or to other contrast agents is not an absolute contraindication to the use of diatrizoate meglumine, but calls for extreme caution in administration.

Please consult full Prescribing Information for CYSTOGRAFIN (diatrizoate meglumine injection USP 30%).
https://imaging.bracco.com/us-en/products/fluoroscopy/cystografin

Please consult full Prescribing Information for CYSTOGRAFIN–Dilute (diatrizoate meglumine injection USP 18%).
https://imaging.bracco.com/us-en/products/fluoroscopy/cystografin

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

CYSTOGRAFIN is manufactured for Bracco Diagnostics Inc., Monroe Township, NJ 08831, by Patheon Italia S.p.A., Ferentino (Italy).

GASTROGRAFIN® (diatrizoate meglumine and diatrizoate sodium solution USP)

Indications and Usage:

GASTROGRAFIN® (diatrizoate meglumine and diatrizoate sodium solution USP) is indicated for radiographic examination of segments of the gastrointestinal tract (esophagus, stomach, proximal small intestine, and colon). The preparation is particularly indicated when a more viscous agent such as barium sulfate, which is not water-soluble, is not feasible or is potentially dangerous.

GASTROGRAFIN (diatrizoate meglumine and diatrizoate sodium solution USP) may also be used as an adjunct to contrast enhancement in computed tomography of the torso (body imaging); the preparation is indicated, in conjunction with intravenous administration of a radiopaque contrast agent, when unenhanced imaging may not provide sufficient definition in distinguishing normal loops of bowel from adjacent organs or areas of suspected pathology.

IMPORTANT SAFETY INFORMATION:

Not for parenteral use; do not inject. For oral or rectal administration only. It should be kept in mind that serious or anaphylactoid reactions that may occur with intravascular administration of radiopaque contrast agents are theoretically possible following administration by other routes. Patients at increased risk include those with a history of a previous reaction to a contrast medium, patients with a known sensitivity to iodine per se, and patients with a known clinical hypersensitivity (bronchial asthma, hay fever and food allergies).

Please see full Prescribing Information for GASTROGRAFIN (diatrizoate meglumine and diatrizoate sodium solution USP). https://imaging.bracco.com/us-en/products/ct-ct-colonography/gastrografin

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

GASTROGRAFIN is manufactured for Bracco Diagnostics Inc., Monroe Township, NJ 08831 by E-Z-EM Canada Inc.

LUMASON® (sulfur hexafluoride lipid-type A microspheres) for injectable suspension, for intravenous use or intravesical use

INDICATIONS AND USAGE

LUMASON® (sulfur hexafluoride lipid-type A microspheres) for injectable suspension, for intravenous use or intravesical use is an ultrasound contrast agent indicated for use:

- in echocardiography to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border in adult and pediatric patients with suboptimal echocardiograms
- in ultrasonography of the liver for characterization of focal liver lesions in adult and pediatric patients
- in ultrasonography of the urinary tract for the evaluation of suspected or known vesicoureteral reflux in pediatric patients

CONTRAINDICATIONS

LUMASON® (sulfur hexafluoride lipid-type A microspheres) for injectable suspension, for intravenous use or intravesical use is contraindicated in patients with known or suspected:

- Hypersensitivity to sulfur hexafluoride lipid microsphere or its components, such as polyethylene glycol (PEG).

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS CARDIOPULMONARY REACTIONS

Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or following the injection of ultrasound contrast agents, including sulfur hexafluoride lipid microspheres *[see Warnings and Precautions (5.1)]*. Most serious reactions occur within 30 minutes of administration *[see Warnings and Precautions (5.1)]*.

- **Assess all patients for the presence of any condition that precludes administration *[see Contraindications (4)]*.**
- **Always have resuscitation equipment and trained personnel readily available *[see Warnings and Precautions (5.1)]*.**

The risk for serious cardiopulmonary reactions may be increased among patients with unstable cardiopulmonary conditions (acute myocardial infarction, acute coronary artery syndromes, worsening or unstable congestive heart failure, or serious ventricular arrhythmias) *[see Warnings and Precautions (5.1)]*. In postmarketing use, serious hypersensitivity reactions have uncommonly been observed during or shortly following the injection of Lumason, including: anaphylaxis, with manifestations that may include death, shock, bronchospasm, dyspnea, throat tightness, angioedema, edema (pharyngeal, palatal, mouth, peripheral, localized), swelling (face, eye, lip, tongue, upper airway), facial hypoesthesia, rash, urticaria, pruritus, flushing, and erythema. These reactions may occur in patients with no history of prior exposure to sulfur hexafluoride lipid-containing microspheres. Lumason contains PEG. There may be increased risk of serious reactions including death in patients with prior hypersensitivity reaction(s) to PEG *[see Adverse Reactions (6.2)]*. Clinically assess patients for prior hypersensitivity reactions to products containing PEG, such as certain colonoscopy bowel preparations and laxatives. Always have cardiopulmonary resuscitation personnel and equipment readily available prior to Lumason administration and monitor all patients for hypersensitivity reactions. The most common adverse reactions are headache and nausea *[see Adverse Reactions (6.1)]*.

Please see full Prescribing Information for LUMASON ultrasound contrast agent including boxed **WARNING** at https://www.braccoimaging.com/us-en/products/contrast-enhanced-ultrasound/lumason

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

LUMASON is manufactured for Bracco Diagnostics Inc., Monroe Township, NJ 08831 by Bracco Suisse S.A., Plan-les-Ouates Geneve, Switzerland (LUMASON lyophilized powder vial-25 mg lipid-type A/60.7 sulfur hexafluoride gas); Vetter Pharma-Fertigung GmbH & Co. KG, 88212 Ravensburg, Germany (Sodium Chloride 0.9% Injection, USP); B. Braun Melsungen AG, 34212 Melsungen, Germany (Mini-Spike).

CARDIOGEN-82® (Rubidium Rb 82 Generator)

Indications and Usage:

CARDIOGEN-82® (Rubidium Rb 82 Generator) is a closed system used to produce rubidium Rb 82 chloride injection for intravenous administration. Rubidium Rb 82 chloride injection is a radioactive diagnostic agent indicated for Positron Emission Tomography (PET) imaging of the myocardium under rest or pharmacologic stress conditions to evaluate regional myocardial perfusion in adult patients with suspected or existing coronary artery disease.

IMPORTANT SAFETY INFORMATION:

WARNING: HIGH LEVEL RADIATION EXPOSURE WITH USE OF INCORRECT ELUENT AND FAILURE TO FOLLOW THE ELUATE TESTING PROTOCOL

Please see full prescribing information for complete boxed warning

High Level Radiation Exposure with Use of Incorrect Eluent

Using the incorrect eluent can cause high Strontium (Sr) 82 and Sr 85 breakthrough levels (5.1)

- **Use only additive-free 0.9% Sodium Chloride Injection USP to elute the generator (2.5)**
- **Immediately stop the patient infusion and permanently discontinue the use of the affected CARDIOGEN-82 generator if the incorrect solution is used to elute the generator (4)**
- **Evaluate the patient's radiation absorbed dose and monitor for the effects of radiation to critical organs such as bone marrow (2.10)**

Excess Radiation Exposure with Failure to Follow the Eluate Testing Protocol

Excess radiation exposure occurs when the levels of Sr 82 or Sr 85 in the rubidium Rb 82 chloride injection exceed limits. (5.2)

- **Record eluate volume, including waste and test volumes. (2.5)**
- **Strictly adhere to the generator eluate testing protocol (2.6, 2.7)**
- **Stop using the generator if it reaches any of its Expiration Limits (2.8)**

Please see full Prescribing Information for CARDIOGEN-82 (Rubidium Rb 82 Generator) including boxed WARNING at. https://imaging.bracco.com/us-en/products/nuclear-medicine-radiopharmaceuticals/cardiogen-82

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

CARDIOGEN-82 is manufactured for Bracco Diagnostics Inc., Monroe Township, NJ 08831, by GE Healthcare, Medi-Physics, Inc., South Plainfield, NJ 07080.

Kinevac® (sincalide for injection)

Indications and Usage:

Kinevac® (sincalide for injection) may be used: (1) to stimulate gallbladder contraction, as may be assessed by various methods of diagnostic imaging, or to obtain by duodenal aspiration a sample of concentrated bile for analysis of cholesterol, bile salts, phospholipids, and crystals; (2) to stimulate pancreatic secretion (especially in conjunction with secretin) prior to obtaining a duodenal aspirate for analysis of enzyme activity, composition, and cytology; (3) to accelerate the transit of a barium meal through the small bowel, thereby decreasing the time and extent of radiation associated with fluoroscopy and x-ray examination of the intestinal tract.

IMPORTANT SAFETY INFORMATION:

Kinevac (sincalide for injection) is contraindicated in patients hypersensitive to sincalide and in patients with intestinal obstruction. Because of Kinevac's effect on smooth muscle, pregnant patients should be advised that spontaneous abortion or premature induction of labor may occur. Adverse reactions to sincalide are generally mild and of short duration. The most frequent adverse reactions were abdominal discomfort or pain, and nausea.

Please consult full Prescribing Information for Kinevac (sincalide for injection) https://imaging.bracco.com/us-en/products/nuclear-medicine-radiopharmaceuticals/kinevac

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Kinevac is manufactured for Bracco Diagnostics Inc., Monroe Township, NJ 08831, by Jubilant HollisterStier LLC, Spokane, WA 99207.

VARIBAR® (barium sulfate)

Indications and Usage:

VARIBAR® THIN HONEY (barium sulfate) oral suspension, VARIBAR® NECTAR (barium sulfate) oral suspension, and VARIBAR® THIN LIQUID (barium sulfate) for oral suspension, are indicated for use in modified barium swallow examinations to evaluate the oral and pharyngeal function and morphology in adult and pediatric patients. VARIBAR® HONEY (barium sulfate) oral suspension and VARIBAR® PUDDING (barium sulfate) oral paste are indicated for use in modified barium swallow examinations to evaluate the oral and pharyngeal function and morphology in adult and pediatric patients 6 months of age and older.

IMPORTANT SAFETY INFORMATION:

For Oral Administration. This product should not be used in patients with known or suspected perforation of the GI tract, known obstruction of the GI tract, high risk of aspiration, or hypersensitivity to barium sulfate products. Rarely, severe allergic reactions of anaphylactoid nature have been reported following administration of barium sulfate contrast agents. Aspiration may occur during the modified barium swallow examination, monitor the patient for aspiration.

Please consult full Prescribing Information for VARIBAR products at https://imaging.bracco.com/us-en/products/fluoroscopy/varibar

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

VARIBAR is manufactured by E-Z-EM Canada Inc., for E-Z-EM, Inc., a subsidiary of Bracco Diagnostics Inc., Monroe Twp., NJ 08831.

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