Bracco Diagnostics Inc.

Product HCPCS Codes

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

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/payment/all-fee-service-providers/medicare-part-b-drug-average-sales-price/asp-pricing-files

For billing purposes when an 11 digit NDC number is required, please add an additional 0 at the beginning of each NDC number.

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Vueway®
(gadopiclenol) injection
485.1 mg/mL

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

VUEWAY® Injection

HCPCS Codes	Product Description	CMS Product Abbreviations	Product SKU	NDC	Unit Size	HCPCS Dosage	HCPCS Billing Units
A9573	VUEWAY® (gadopiclenol) solution for injection, 485.1 mg/mL	Injection, gadopiclenol, 1 mL	702038	0270-7020-38	10 x 3 mL vials/box	1mL	3
A9573	VUEWAY® (gadopiclenol) solution for injection, 485.1 mg/mL	Injection, gadopiclenol, 1 mL	702540	0270-7025-40	10 x 7.5 mL vials/box	1mL	7.5
A9573	VUEWAY® (gadopiclenol) solution for injection, 485.1 mg/mL	Injection, gadopiclenol, 1 mL	703042	0270-7030-42	10 x 10 mL vials/box	1mL	10

VUEWAY® Pharmacy Bulk Package

HCPCS Codes	Product Description	CMS Product Abbreviations	Product SKU	NDC	Unit Size	HCPCS Dosage	HCPCS Billing Units
A9573	VUEWAY® (gadopiclenol) solution for injection, 485.1 mg/mL	Injection, gadopiclenol, 1 mL	701546	0270-7015-46	25 x 30 mL vials/box	1mL	30
A9573	VUEWAY® (gadopiclenol) solution for injection, 485.1 mg/mL	Injection, gadopiclenol, 1 mL	701548	0270-7015-48	25 x 50 mL vials/box	1mL	50

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

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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

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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. ProHance Multipack	1111-70	0270-1111-70	5 x 50 mL bottles/box	1mL	50
A9576	ProHance® Multipack™ (Gadoteridol) Injection, 279.3 mg/mL	Inj. ProHance Multipack	1111-85	0270-1111-85	5 x 100 mL bottles/box	1mL	100

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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

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GASTROGRAFIN®

(diatrizoate meglumine and diatrizoate sodium solution USP)

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
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

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ISOVUE®
(iopamidol injection)

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

ISOVUE®-200 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

ISOVUE®-250 Contrast Agent

HCPCS Codes	Product Description	CMS Product Abbreviations	Product SKU	NDC	Unit Size	HCPCS Dosage	HCPCS Billing Units
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

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ISOVUE®
(iopamidol injection)

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

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	1315-35	0270-1315-35	10 x 100 mL bottles /case	1mL	100

ISOVUE®-300 Imaging Bulk Package

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

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ISOVUE®
(iopamidol injection)

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

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	1316-35	0270-1316-35	10 x 100 mL bottles/case	1mL	100

ISOVUE®-370 Imaging Bulk Package

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

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ISOVUE-M®
(iopamidol injection)

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

ISOVUE-M® 200 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

ISOVUE-M® 300 Contrast Agent

HCPCS Codes	Product Description	CMS Product Abbreviations	Product SKU	NDC	Unit Size	HCPCS Dosage	HCPCS Billing Units
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

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LUMASON®

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

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 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

HCPCS Codes	Product Description	CMS Product Abbreviations	Product SKU	NDC	Unit Size	HCPCS Dosage	HCPCS Billing Units Per Vial
Q9950	LUMASON Novaplus®	Inj sulf hexa lipid microsph	709700	0270-7099-73	5 x 5 mL vials per box	1mL	5
Q9950	LUMASON Novaplus®	Inj sulf hexa lipid microsph	709708	0270-7097-08	20 x 5 mL vials per box	1mL	5

Available to purchase direct from Bracco Diagnostics Inc. and through authorized wholesale distributors.
Novaplus is a registered trademark of Vizient, Inc.

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Cardiogen-82™

(Rubidium Rb 82 Generator)

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	HCPCS Dosage
A9555	CARDIOGEN-82® (Rubidium Rb 82 Generator)	Rubidium Rb-82	0091-01	0270-0091-01	Per study dose, up to 60 mCi

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Kinevac®

Sincalide for Injection

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 Billing Units
J2805	Kinevac® (sincalide for injection)	Sincalide Inj	0556-15	0270-0556-15	10 x 5 mcg 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.

Product Description	Product SKU	NDC	Unit Size
VARIBAR® HONEY (barium sulfate) oral suspension	900005	32909-122-07	12 x 250 mL bottles/case
VARIBAR® NECTAR (barium sulfate) oral suspension	705700	32909-116-00	12 x 240 mL bottles/case
VARIBAR® PUDDING (barium sulfate) oral paste	900006	32909-125-22	12 x 230 mL bottles/case
VARIBAR® THIN HONEY (barium sulfate) oral suspension	900004	32909-121-07	12 x 250 mL bottles/case
VARIBAR® THIN LIQUID (barium sulfate) for oral suspension	900001	32909-105-10	24 x 148 g bottles/case

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.

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 November 20, 2023

Vueway®
(gadopiclenol) injection
485.1 mg/mL

VUEWAY® (gadopiclenol) solution for injection

Indications
VUEWAY injection is indicated in adults and children aged 2 years and older for use with magnetic resonance imaging (MRI) to detect and visualize lesions with abnormal vascularity in:

- the central nervous system (brain, spine and surrounding tissues),
- the body (head and neck, thorax, abdomen, pelvis, and musculoskeletal system).

IMPORTANT SAFETY INFORMATION

WARNING: RISK ASSOCIATED WITH INTRATHECAL USE and NEPHROGENIC SYSTEMIC FIBROSIS

Risk Associated with Intrathecal Use

Intrathecal administration of gadolinium-based contrast agents (GBCAs) can cause serious adverse reactions including death, coma, encephalopathy, and seizures. VUEWAY is not approved for intrathecal use.

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 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/1.73 m^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, diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing.**
- **For patients at highest risk for NSF, do not exceed the recommended VUEWAY dose and allow a sufficient period of time for elimination of the drug from the body prior to any re-administration.**

Contraindications
VUEWAY injection is contraindicated in patients with history of hypersensitivity reactions to VUEWAY.

Warnings and Precautions
There are **risks associated with intrathecal use** of GBCAs that can cause serious adverse reactions including death, coma, encephalopathy, and seizures. The safety and effectiveness of VUEWAY have not been established with intrathecal use and VUEWAY is not approved for intrathecal use.

Risk of **nephrogenic systemic fibrosis** is increased in patients using GBCA agents that have impaired elimination of the drugs, with the highest risk in patients with chronic, severe kidney disease as well as patients with acute kidney injury. Avoid use of GBCAs among these patients unless the diagnostic information is essential and not available with non-contrast MRI or other modalities.

Hypersensitivity reactions, including serious hypersensitivity reactions, could occur during use or shortly following VUEWAY administration. Assess all patients for any history of a reaction to contrast media, bronchial asthma and/or allergic disorders, administer VUEWAY only in situations where trained personnel and therapies are promptly available for the treatment of hypersensitivity reactions, and observe patients for signs and symptoms of hypersensitivity reactions after administration.

Gadolinium retention can be for months or years in several organs after administration. The highest concentrations (nanomoles per gram of tissue) have been identified in the bone, followed by other organs (brain, skin, kidney, liver and spleen). Minimize repetitive GBCA imaging studies, particularly closely spaced studies, when possible.

Acute kidney injury requiring dialysis has occurred with the use of GBCAs in patients with chronically reduced renal function. The risk of acute kidney injury may increase with increasing dose of the contrast agent.

Extravasation and injection site reactions can occur with administration of VUEWAY. Ensure catheter and venous patency before the injection of VUEWAY.

VUEWAY may **impair the visualization of lesions** seen on non-contrast MRI. Therefore, caution should be exercised when VUEWAY MRI scans are interpreted without a companion non-contrast MRI scan.

The most common adverse reactions (incidence ≥ 0.5%) are injection site pain (0.7%), and headache (0.7%).

POST-MARKETING EVENTS
The following adverse reactions have been identified during postmarketing use of GBCAs.
Gastrointestinal Disorders: Acute pancreatitis with onset within 48 hours after GBCA administration

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.

Please click here for full Prescribing Information for VUEWAY (gadopiclenol) solution for injection including BOXED WARNING on Nephrogenic Systemic Fibrosis.

Manufactured for Bracco Diagnostics Inc. by Liebel-Flarsheim Company LLC - Raleigh, NC, USA 27616.

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

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
- Magnetic resonance angiography (MRA) to evaluate adults with known or suspected renal or aorto-ilio-femoral occlusive vascular disease

IMPORTANT SAFETY INFORMATION
WARNING: RISK ASSOCIATED WITH INTRATHECAL USE and NEPHROGENIC SYSTEMIC FIBROSIS

Risk Associated with Intrathecal Use
Intrathecal administration of gadolinium-based contrast agents (GBCAs) can cause serious adverse reactions including death, coma, encephalopathy, and seizures. MultiHance is not approved for intrathecal use.

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 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/1.73 m²), 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, 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 any re-administration.**

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

WARNINGS AND PRECAUTIONS
Risk Associated with Intrathecal Use: Intrathecal administration of GBCAs can cause serious adverse reactions including death, coma, encephalopathy, and seizures. The safety and effectiveness of MultiHance have not been established with intrathecal use and MultiHance is not approved for intrathecal use.
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%).

POST-MARKETING EVENTS
The following adverse reactions have been identified during post approval use of MultiHance or other GBCAs:
Acute pancreatitis within 48 hours of GBCA administration has been reported.
Respiratory, Thoracic and Mediastinal Disorders: Acute respiratory distress syndrome, pulmonary edema.

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.

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.

Please click here for Prescribing Information and Patient Medication Guide for additional important safety information for/regarding MultiHance (gadobenate dimeglumine) injection, 529 mg/mL.

Please click here for Prescribing Information and Patient Medication Guide for additional important safety information for/regarding MultiHance Multipack.

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

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

Indications and Usage:
CENTRAL NERVOUS SYSTEM
ProHance 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 TISSUES
ProHance is indicated for use in MRI in adults to visualize lesions in the head and neck.

IMPORTANT SAFETY INFORMATION

WARNING: RISK ASSOCIATED WITH INTRATHECAL USE and NEPHROGENIC SYSTEMIC FIBROSIS

Risk Associated with Intrathecal Use
Intrathecal administration of gadolinium-based contrast agents (GBCAs) can cause serious adverse reactions including death, coma, encephalopathy, and seizures. ProHance is not approved for intrathecal use.

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/1.73m2), 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.**
- **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
Risk Associated with Intrathecal Use: Intrathecal administration of GBCAs can cause serious adverse reactions including death, coma, encephalopathy, and seizures. The safety and effectiveness of ProHance have not been established with intrathecal use and ProHance is not approved for intrathecal use.
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%.

POST-MARKETING EVENTS
The following adverse reactions have been identified during post approval use of Prohance or other GBCAs:
Acute pancreatitis within 48 hours of GBCA administration has been reported.
Respiratory, Thoracic and Mediastinal Disorders: Acute respiratory distress syndrome, pulmonary edema.

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.

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.

Please click here for full Prescribing Information and Patient Medication Guide for additional important safety information for/regarding ProHance (Gadoteridol) Injection, 279.3 mg/mL.

Please click here for full Prescribing Information and Patient Medication Guide for additional important safety information for/regarding ProHance Multipack.

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

CYSTOGRAFIN®
(diatrizoate meglumine injection USP 30%)

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

Cystografin® (Diatrizoate Meglumine Injection USP 30%) and Cystografin Dilute® (Diatrizoate Meglumine Injection USP 18%)

INDICATION
Cystografin® and Cystografin Dilute® are indicated for retrograde cystourethrography.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
Contraindicated in patients with a hypersensitivity to salts of diatrizoic acid.

WARNINGS AND PRECAUTIONS
Severe sensitivity reactions are more likely to occur in patients with a personal or family 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.

Safe and effective use of this preparation depends upon proper dosage, correct technique, adequate precautions, and readiness for emergencies.

Retrograde cystourethrography should be performed with caution in patients with a known active infectious process of the urinary tract.

Sterile technique should be employed in administration. During administration, care should be taken to avoid excessive pressure, rapid or acute distention of the bladder, and trauma.

Contrast agents may interfere with some chemical determinations made on urine specimens; therefore, urine should be collected before administration of the contrast medium or two or more days afterward.

Pregnancy–Teratogenic Effects
It is also not known whether diatrizoate meglumine injection can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. [Cystografin or Cystografin Dilute] should be administered to a pregnant woman only if clearly needed.

ADVERSE REACTIONS
Retrograde genitourinary procedures may cause hematuria, perforation of the urethra or bladder, the introduction of infection into the genitourinary tract, and oliguria or anuria.

If intravasation of this drug occurs, the reactions which may be associated with intravenous administration may possibly be encountered. Hypersensitivity or anaphylactoid reactions may occur. Severe reactions may be manifested by edema of the face and glottis, respiratory distress, convulsions, or shock; such reactions may prove fatal unless promptly controlled by such emergency measures as maintenance of a clear airway and immediate use of oxygen and resuscitative drugs.

Endocrine: Thyroid function tests indicative of hypothyroidism or transient thyroid suppression have been uncommonly reported following iodinated contrast media administration to adult and pediatric patients, including infants. Some patients were treated for hypothyroidism.

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.

Please click here for full Prescribing Information for Cystografin® (Diatrizoate Meglumine Injection USP 30%).

Please click here for full Prescribing Information for Cystografin Dilute® (Diatrizoate Meglumine Injection USP 18%).

CYSTOGRAFIN is manufactured for Bracco Diagnostics Inc., Princeton, NJ 08540, by Patheon Italia S.p.A., Ferentino (Italy).

GASTROGRAFIN®
(diatrizoate meglumine and diatrizoate sodium solution USP)

GASTROGRAFIN® (Diatrizoate Meglumine and Diatrizoate Sodium Solution USP)

INDICATION
Gastrografin (Diatrizoate Meglumine and Diatrizoate Sodium Solution) 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 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.

CONTRAINDICATIONS
Do not administer to patients with a known hypersensitivity to Gastrografin or any of its components.

WARNINGS AND PRECAUTIONS
Dehydration: Administration of hypertonic Gastrografin solutions may lead to hypovolemia and hypotension due to fluid loss from the intestine. Less dilute solutions are hypertonic and may lead to intraluminal movement of fluid with resulting hypovolemia. In young or debilitated children and in elderly cachectic persons, the loss of plasma fluid may be sufficient to cause a shock-like state. If Gastrografin is used in infants and children (under 10 kg) or in dehydrated or debilitated patients, prepare the solution using the specific dilutions described in DOSAGE AND ADMINISTRATION. In debilitated patients and in patients with electrolyte imbalances, postprocedural monitoring of hydration, serum osmolarity, electrolytes, and clinical status is essential. In pediatric or severely debilitated patients, maintain an open intravenous fluid line for rehydration should hypotension or shock supervene. Correct electrolyte disturbances prior to any hypertonic Gastrografin solutions administration.

Aspiration: Aspiration of Gastrografin into the trachea and airways may result in serious pulmonary complications including, pulmonary edema, pneumonitis, or death. Bronchial entry of any orally administered contrast medium causes a copious osmotic effusion. Avoid the use of Gastrografin in patients with esophagotracheal fistula and minimize risks for pulmonary aspiration in all patients. If Gastrografin is given by nasogastric tube, verify the position of the tube in the stomach before administration.

Anaphylactic reactions: Anaphylactic reactions, including fatalities, have been reported. Patients with a history of a previous reaction to a contrast medium, known sensitivity to iodine, and known clinical hypersensitivity (bronchial asthma, hay fever, and food allergies) are at increased risk. Medical personnel trained in the treatment of anaphylactic reactions, necessary drugs, and medical equipment should be readily available when Gastrografin is used.

Diagnostic procedures: using radiopaque contrast agents should be carried out under the direction of personnel with the prerequisite training and with a thorough knowledge of the particular procedure to be performed. Appropriate facilities should be available for coping with any complication of administration, as well as for treatment of reaction to the contrast medium.

Rectal administration: of undiluted Gastrografin in any patient, particularly with large doses and/or in those with overdistention, has been reported to be associated with mucosal irritation.

Hyperthyroidism: Cases of hyperthyroidism have been reported with the use of oral contrast media. Some patients had multinodular goiters which may have been responsible for the increased hormone synthesis in response to excess iodine. Administration of an intravascular iodinated radiopaque diagnostic agent to a hyperthyroid patient precipitated thyroid storm; a similar situation could follow the administration of oral preparations of iodides. Use caution when administering enteral gastrointestinal radiopaque agents to hyperthyroid and euthyroid goiterous patients.

Hyperacidity Conditions: The potential for precipitation of water-soluble contrast agents under conditions that may promote hyperacidity (i.e., fasting, emotional upset, or stress) should be considered. The possibility of interpreting the precipitate radiologically as an anatomical abnormality (i.e., ulceration of the stomach or small intestine) or injury, should be kept in mind.

ADVERSE REACTIONS
Most adverse reactions to enteral diagnostic radiopaque agents are mild and transitory. Nausea, vomiting and/or diarrhea, urticaria with erythema, hypoxia, acute dyspnea, tachyarrhythmia, and anaphylaxis have occurred following ingestion of the contrast medium, particularly when high concentrations of large volumes of solution are administered. Severe changes in serum osmolarity and electrolyte concentrations may produce shock-like states. 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.

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.

Please click here for full Prescribing Information for Gastrografin® (Diatrizoate Meglumine and Diatrizoate Sodium Solution USP).

GASTROGRAFIN is manufactured for Bracco Diagnostics Inc., Princeton, NJ 08540 by E-Z-EM Canada Inc.

ISOVUE®
(iopamidol injection)

BRACCO
LIFE FROM INSIDE

ISOVUE® (Iopamidol Injection)

INDICATION:
ISOVUE®-200, -250, -300, -370 (Iopamidol Injection)
ISOVUE®-300, -370 (Iopamidol Injection) Imaging Bulk Package is indicated for:

- angiography in adults throughout the cardiovascular system including cerebral and peripheral arteriography, coronary arteriography and ventriculography, selective visceral arteriography and aortography
- in pediatric patients for angiocardiography
- in adult and pediatric intravenous excretory urography
- contrast enhancement of computed tomographic (CECT) head and body imaging
- peripheral venography in adults

WARNING: RISKS ASSOCIATED WITH INTRATHECAL ADMINISTRATION
Intrathecal administration, even if inadvertent, can cause death, convulsions, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, seizures, rhabdomyolysis, hyperthermia, and brain edema. ISOVUE is for intra-arterial or intravenous use only.

IMPORTANT SAFETY INFORMATION:

WARNINGS AND PRECAUTIONS
Risks Associated with Intrathecal Administration
Intrathecal administration, even if inadvertent, can cause death, convulsions, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, seizures, rhabdomyolysis, hyperthermia, and brain edema. ISOVUE is for intra-arterial or intravenous use only and must not be administered intrathecally.

Hypersensitivity Reactions
ISOVUE can cause life-threatening or fatal hypersensitivity reactions including anaphylaxis.
Manifestations include respiratory arrest, laryngospasm, bronchospasm, angioedema, and shock. Most severe reactions develop shortly after the start of injection (e.g., within 1 to 3 minutes), but delayed reactions can also occur. There is increased risk of hypersensitivity reactions in patients with a history of previous reactions to contrast agents, and allergic disorders (i.e., bronchial asthma, allergic rhinitis, and food allergies) or other hypersensitivities. Obtain a history of allergy, hypersensitivity, or hypersensitivity reactions to iodinated contrast agents and always have emergency resuscitation equipment and trained personnel available prior to ISOVUE administration. Monitor all patients for hypersensitivity reactions.

Acute Kidney Injury
Acute kidney injury, including renal failure, may occur after ISOVUE administration. Risk factors include: pre-existing renal insufficiency, dehydration, diabetes mellitus, congestive heart failure, advanced vascular disease, elderly age, concomitant use of nephrotoxic or diuretic medications, multiple myeloma or other paraproteinemias, and repetitive or large doses of ISOVUE. Use the lowest necessary dose of ISOVUE in patients with renal impairment. Adequately hydrate patients prior to and following ISOVUE administration. Do not use laxatives, diuretics, or preparatory dehydration prior to ISOVUE administration.

Cardiovascular Adverse Reactions
ISOVUE increases the circulatory osmotic load and may induce acute or delayed hemodynamic disturbances in patients with congestive heart failure, severely impaired renal function, combined renal and hepatic disease, and combined renal and cardiac disease, particularly when repetitive or large doses are administered. Fatal cardiovascular reactions have occurred mostly within 10 minutes of ISOVUE injection; the main feature was cardiac arrest with cardiovascular disease as the main underlying factor. Hypotensive collapse and shock have occurred. Cardiac decompensation, serious arrhythmias, and myocardial ischemia or infarction can occur during coronary arteriography and ventriculography. Use the lowest necessary dose of ISOVUE in patients with congestive heart failure and always have emergency resuscitation equipment and trained personnel available. Monitor all patients for severe cardiovascular reactions.

Thromboembolic Events
Serious, in some cases fatal, thromboembolic events, including myocardial infarction and stroke, can occur during angiographic procedures. During these procedures, increased thrombosis and activation of the complement system occurs. Risk factors for developing thromboembolic events include: length of procedure, catheter and syringe material, underlying disease state, and concomitant medications. To minimize thromboembolic events, use meticulous angiographic techniques and minimize the length of the procedure. Avoid blood remaining in contact with syringes containing iodinated contrast agents, which increases risk of clotting. Avoid angiocardiography in patients with homocystinuria because of the risk of inducing thrombosis and embolism.

Extravasation and Injection Site Reactions
Extravasation can occur with ISOVUE administration, particularly in patients with severe arterial or venous disease. Inflammation, blistering, skin necrosis, and compartment syndrome have been reported following extravasation. In addition, injection site reactions such as pain and swelling at the injection site can also occur. Ensure intravascular placement of catheters prior to injection. Monitor patients for extravasation and advise patients to seek medical care for progression of symptoms.

Thyroid Storm in Patients with Hyperthyroidism
Thyroid storm has occurred after the intravascular use of iodinated agents in patients with hyperthyroidism or with an autonomously functioning thyroid nodule. Evaluate the risk in such patients before use of ISOVUE.

Thyroid Dysfunction in Pediatric Patients 0 Years to 3 Years of Age
Thyroid dysfunction characterized by hypothyroidism or transient thyroid suppression has been reported after both single exposure and multiple exposures to iodinated contrast agents in pediatric patients 0 years to 3 years of age. Younger age, very low birth weight, prematurity, underlying medical conditions affecting thyroid function, admission to neonatal or pediatric intensive care units, and congenital cardiac conditions are associated with an increased risk of hypothyroidism after iodinated contrast agent exposure. Pediatric patients with congenital cardiac conditions may be at greatest risk given that they often require high doses of contrast during invasive cardiac procedures. An underactive thyroid during early life may be harmful for cognitive and neurological development and may require thyroid hormone replacement therapy. After exposure to iodinated contrast agents, individualize thyroid function monitoring based on underlying risk factors, especially in term and preterm neonates.

Hypertensive Crisis in Patients with Pheochromocytoma
Hypertensive crisis in patients with pheochromocytoma has occurred with iodinated contrast agents. Closely monitor patients when administering ISOVUE if pheochromocytoma or catecholamine-secreting7 of 13 paragangliomas are suspected. Inject the minimum amount of ISOVUE necessary and have measures for treatment of hypertensive crisis readily available.

Sickle Cell Crisis in Patients with Sickle Cell Disease
Iodinated contrast agents can promote sickling in individuals who are homozygous for sickle cell disease. Hydrate patients prior to and following ISOVUE administration and use only if the necessary imaging information cannot be obtained with alternative imaging modalities.

Severe Cutaneous Adverse Reactions
Severe cutaneous adverse reactions (SCAR) may develop from 1 hour to several weeks after intravascular contrast agent administration. These reactions include Stevens-Johnson syndrome and toxic epidermal necrolysis (SJS/TEN), acute generalized exanthematous pustulosis (AGEP), and drug reaction with eosinophilia and systemic symptoms (DRESS). Reaction severity may increase and time to onset may decrease with repeat administration of a contrast agent; prophylactic medications may not prevent or mitigate severe cutaneous adverse reactions. Avoid administering ISOVUE to patients with a history of a severe cutaneous adverse reaction to ISOVUE.

Interference with Laboratory Tests
ISOVUE can interfere with protein-bound iodine test.

ADVERSE REACTIONS
The most frequent adverse reactions are pain, hot flashes, burning sensation, nausea, and warmth.

DRUG INTERACTIONS
Metformin: In patients with renal impairment, metformin can cause lactic acidosis. Iodinated contrast agents appear to increase the risk of metformin-induced lactic acidosis, possibly as a result of worsening renal function.

Radioactive Iodine: Administration of ISOVUE may interfere with thyroid uptake of radioactive iodine (I-131 and I-123) and decrease therapeutic and diagnostic efficacy. Avoid thyroid therapy or testing for up to 6 weeks post ISOVUE.

USE IN SPECIFIC POPULATIONS
Geriatric Use: Iopamidol is excreted by the kidney, and the risk of adverse reactions to ISOVUE may be greater in patients with renal impairment. Because patients 65 years of age and older are more likely to have renal impairment, care should be taken in dose selection, and it may be useful to monitor renal function.

Renal Impairment: The clearance of iopamidol decreases with increasing degree of renal impairment and results in delayed opacification of the urinary system. In addition, preexisting renal impairment increases the risk for acute kidney injury. Iopamidol can be removed by dialysis.

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.

Please click here for full Prescribing Information for ISOVUE® products.

Please click here for full Prescribing Information for ISOVUE® Imaging Bulk Package products.

ISOVUE and ISOVUE Imaging Bulk Package 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).

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LIFE FROM INSIDE

ISOVUE-M®
(iopamidol injection)

ISOVUE-M® 200, 300 (Iopamidol Injection)

INDICATION:

ISOVUE-M® 200, 300 (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 is indicated for thoraco-lumbar myelography in children over the age of two years.

CONTRAINDICATION:
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.

IMPORTANT SAFETY INFORMATION:

WARNINGS AND PRECAUTIONS
The need for myelographic examination should be carefully evaluated. Caution should be taken when administering ISOVUE-M to 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 the state of hydration, concentration of medium, dose, and technique used in these patients.

Risk of Neurotoxicity
Prevent inadvertent intracranial entry of a large or concentrated bolus of the contrast medium which can increase the risk of neurotoxicity through careful patient management. Avoid rapid dispersion of the medium causing inadvertent rise to intracranial levels (e.g., by active patient movement). If intracranial entry of the medium occurs, prophylactic anticonvulsant treatment with diazepam or barbiturates orally for 24 to 48 hours should be considered.

Lowered Seizure Threshold
Phenothiazine derivatives, including those used for their antihistaminic properties; tricyclic antidepressants; MAO inhibitors; CNS stimulants; analeptics; and antipsychotic agents should be carefully evaluated as they may lower the seizure threshold. Some physicians have discontinued these agents at least 48 hours before and for at least 24 hours following intrathecal use.

Focal and Generalized Motor Seizures
In several cases where higher than recommended doses of iopamidol were administered, focal and generalized motor seizures were reported. Therefore avoid:

- Deviations from recommended neuroradiologic procedure or patient management.
- Use in patients with a history of epilepsy unless medically justified.
- Overdosage.
- Intracranial entry of a bolus or premature diffusion of a high concentration of the medium.
- Failure to maintain elevation of the head during the procedure, on the stretcher, and in bed.
- Excessive and particularly active patient movement or straining.

Hypersensitivity /Anaphylaxis
Patients at increased risk include those with a history of a previous reaction to a contrast medium, with a known sensitivity to iodine, with a known clinical hypersensitivity (bronchial asthma, hay fever, and food allergies). A thorough medical history with emphasis on allergy and hypersensitivity, prior to the injection of any contrast medium, may be more accurate than pretesting in predicting potential adverse reactions.
Premedication with antihistamines or corticosteroids to avoid or minimize possible allergic reactions in such patients should be considered.

DRUG INTERACTION
Many radiopaque contrast agents are incompatible in vitro with some antihistamines and many other drugs. No other pharmaceuticals should be admixed with iopamidol.

ADVERSE REACTIONS
The most frequent adverse reactions are headache, nausea, vomiting, and musculoskeletal pain.

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.

Please click here for full Prescribing Information for ISOVUE-M® products.

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).

BRACCO

LIFE FROM INSIDE

LUMASON®

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

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

Indications

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

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. Most serious reactions occur within 30 minutes of administration.

- **Assess all patients for the presence of any condition that precludes administration**
- **Always have resuscitation equipment and trained personnel readily available**

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).

Warnings

Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or shortly following administration of ultrasound contrast agents, including LUMASON. Always have cardiopulmonary resuscitation personnel and equipment readily available prior to LUMASON administration and monitor all patients for acute reactions.

Post-marketing **hypersensitivity reactions**, including serious hypersensitivity reactions, have been observed during use or shortly following LUMASON administration. 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.

Systemic embolization may occur in patients with cardiac shunts. Assess patients with cardiac shunts for embolic phenomena following LUMASON administration.

There is a risk of **ventricular arrhythmia related to high mechanical index** in patients administered LUMASON. LUMASON is not recommended for use at mechanical indices greater than 0.8.

The most common adverse reactions (incidence ≥ 0.5%) are headache (1%) and nausea (0.5%).

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.

Please click here for full Prescribing Information for LUMASON ultrasound contrast agent, including BOXED WARNING on Serious Cardiopulmonary Reactions.

LUMASON is manufactured for Bracco Diagnostics Inc., Princeton, NJ 08540 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) or Bracco Imaging S.p.A. Via Ribes, 5, 10010 Colleretto Giacosa (TO), Italy (0.9% Sodium Chloride Injection, USP); B. Braun Melsungen AG 34212 Melsungen, Germany (Mini-Spike).

BRACCO
LIFE FROM INSIDE

Cardiogen·82™
(Rubidium Rb 82 Generator)

CARDIOGEN-82® (rubidium Rb 82 generator)

INDICATION

CARDIOGEN-82 is a closed system used to produce rubidium Rb 82 chloride injection for intravenous administration and is 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

High Level Radiation Exposure with Use of Incorrect Eluent

Patients are exposed to high radiation levels when the CardioGen-82 generator is eluted with the incorrect eluent due to high Sr 82 and Sr 85 breakthrough levels.

- **Use only additive-free 0.9% Sodium Chloride Injection USP to elute the generator**
- **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**
- **Evaluate the patient's radiation absorbed dose and monitor for the effects of radiation to critical organs such as bone marrow**

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 specified limits.

- **Record each generator eluate volume, including waste and test volumes, and keep a record of the cumulative eluate volume**
- **Strictly adhere to the generator eluate testing protocol, to minimize the risk of excess radiation exposure, including daily testing and additional testing at Alert Limits**
- **Stop using the generator if it reaches any of its Expiration Limits: 17 L for the generator's cumulative eluate volume, or 42 days post generator calibration date, or an eluate Sr 82 level of 0.01 µCi /mCi Rb 82, or an eluate Sr 85 level of 0.1 µCi /mCi Rb 82**

CONTRAINDICATIONS

CardioGen-82 is contraindicated if a solution other than additive free 0.9% Sodium Chloride Injection USP has been used to elute the generator at any time. Immediately stop the patient infusion and permanently discontinue the use of the affected CardioGen-82 generator whenever the incorrect eluent is used.

WARNINGS AND PRECAUTIONS

High Level Radiation Exposure with Use of Incorrect Eluent

Use only additive free 0.9% Sodium Chloride Injection USP to elute the generator. Apply the provided saline tag to the additive free 0.9% Sodium Chloride Injection USP container before use. Additives present in other solutions (particularly calcium ions) expose patients to high levels of radiation by causing the release of large amounts of Sr 82 and Sr 85 into the eluate regardless of the generator's age or prior use. **Immediately stop the patient infusion and discontinue use of the affected CardioGen-82 generator if the incorrect eluent is used and evaluate the patient's radiation absorbed dose and monitor for the effects of radiation to critical organs such as bone marrow.**

Excess Radiation Exposure with Failure to Follow Testing Protocol

Excess radiation exposure occurs when the Sr 82 and Sr 85 levels in rubidium Rb 82 chloride injections exceed the specified generator eluate limits. Strictly adhere to the eluate testing protocol to minimize radiation exposure to the patient. Stop using the rubidium generator when the expiration limits are reached.

Risk Associated with Pharmacologic Stress

Pharmacologic induction of cardiovascular stress may be associated with serious adverse reactions such as myocardial infarction, arrhythmia, hypotension, bronchoconstriction, and cerebrovascular events. Perform pharmacologic stress testing in accordance with the pharmacologic stress agent's prescribing information and only in the setting where cardiac resuscitation equipment and trained staff are readily available.

Volume Overload

Patients with congestive heart failure or the elderly may experience a transitory increase in circulatory volume load.

Cumulative Radiation Exposure: Long-Term Risk of Cancer

Rubidium Rb 82 chloride injection, similar to other radiopharmaceuticals, contributes to a patient's overall long-term cumulative radiation exposure which is associated with an increased risk of cancer. Use the lowest dose of rubidium Rb 82 chloride injection necessary for imaging and ensure safe handling to protect the patient and health care worker. Encourage patients to void as soon as a study is completed and as often as possible thereafter for at least one hour.

ADVERSE REACTIONS

Radiation Exposure

High level radiation exposure to the bone marrow has occurred in some patients due to Sr 82 and Sr 85 breakthrough in the eluate when an incorrect solution was used to elute the rubidium Rb 82 generator. Excess radiation exposure has occurred in some patients who received rubidium Rb 82 chloride injections at clinical sites where generator eluate testing appeared insufficient.

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.

Please click here for full Prescribing Information for CardioGen-82 (rubidium Rb 82 generator) including boxed WARNING.

CARDIOGEN-82 is manufactured for Bracco Diagnostics Inc., Princeton, NJ 08540, by GE Healthcare, Medi-Physics, Inc., South Plainfield, NJ 07080.

Kinevac®
Sincalide for Injection

KINEVAC® (Sincalide for Injection)

Indications
KINEVAC® (Sincalide for Injection), is indicated in adults 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
- stimulate pancreatic secretion (especially in conjunction with secretin) prior to obtaining a duodenal aspirate for analysis of enzyme activity, composition, and cytology
- 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

Contraindications
KINEVAC is contraindicated in patients with a history of hypersensitivity to sincalide, including anaphylaxis and anaphylactic shock, or in patients with intestinal obstruction.

Warnings and Precautions
Post-marketing **anaphylaxis, anaphylactic shock, and other serious hypersensitivity reactions** have been reported during and within one hour following administration of Kinevac. If anaphylaxis or other hypersensitivity reactions occur, immediately discontinue the infusion and initiate appropriate medical treatment.

Stimulation of gallbladder contraction can lead to **small gallbladder stone evacuation**, resulting in lodging in the cystic duct or in the common bile duct.

Kinevac may cause adverse reactions such as **nausea, vomiting, abdominal pain or cramping, dizziness, and flushing.** To reduce the risk of adverse reactions, administer Kinevac over 50 minutes for simulation of gallbladder contraction or over 30 minutes to accelerate transit of a barium meal through the small intestine.

Pregnant patients should be advised that Kinevac can effect smooth muscle, which may cause spontaneous abortion or premature induction of labor.

The most common adverse reactions (≥ 20%) include abdominal discomfort or pain, and nausea.

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.

Please click here to see the accompanying full Prescribing Information for Kinevac (Sincalide for Injection).

Kinevac is manufactured for Bracco Diagnostics Inc., Princeton, NJ 08540, by Fresenius Kabi USA, LLC, Spokane, WA 99207.

Varibar® (barium sulfate)

VARIBAR® (barium sulfate)

INDICATIONS

VARIBAR® THIN HONEY (barium sulfate) oral suspension, VARIBAR® NECTAR (barium sulfate) oral suspension, and VARIBAR® THIN LIQUID (barium sulfate) oral suspension are radiographic contrast agents 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 radiographic contrast agents 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

CONTRAINDICATIONS

These products should not be used in patients with known or suspected perforation of the gastrointestinal (GI) tract; known obstruction of the GI tract; high risk of GI perforation such as those with a recent GI perforation, acute GI hemorrhage or ischemia, toxic megacolon, severe ileus, post GI surgery or biopsy, acute GI injury or burn, or recent radiotherapy to the pelvis; high risk of aspiration such as those with known or suspected tracheo-esophageal fistula or obtundation; known severe hypersensitivity to barium sulfate or any of the excipients of the product used.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Barium sulfate preparations contain a number of excipients, including natural and artificial flavors, and may induce serious hypersensitivity reactions. The manifestations include hypotension, bronchospasm and other respiratory impairments, and dermal reactions including rashes, urticaria, and itching. A history of bronchial asthma, atopy, food allergies, or a previous reaction to a contrast agent may increase the risk for hypersensitivity reactions. Emergency equipment and trained personnel should be immediately available for treatment of a hypersensitivity reaction.

Intra-abdominal Barium Leakage

The use of VARIBAR PRODUCTS is contraindicated in patients at high risk of perforation of the GI tract. Administration of VARIBAR PRODUCTS may result in leakage of barium from the GI tract in the presence of conditions such as carcinomas, GI fistula, inflammatory bowel disease, gastric or duodenal ulcer, appendicitis, or diverticulitis, and in patients with a severe stenosis at any level of the GI tract, especially if it is distal to the stomach. The barium leakage has been associated with peritonitis and granuloma formation.

Delayed Gastrointestinal Transit and Obstruction

Orally administered barium sulfate may accumulate proximal to a constricting lesion of the colon, causing obstruction or impaction with development of baroliths (inspissated barium associated with feces) and may lead to abdominal pain, appendicitis, bowel obstruction, or rarely perforation. Patients with the following conditions are at higher risk for developing obstruction or baroliths: severe stenosis at any level of the GI tract, impaired GI motility, electrolyte imbalance, dehydration, on a low residue diet, taking medications that delay GI motility, constipation, pediatric patients with cystic fibrosis or Hirschsprung disease, and the elderly. To reduce the risk of delayed GI transit and obstruction, patients should maintain adequate hydration after the barium sulfate procedure. When administering VARIBAR PUDDING, consider the administration of laxatives.

Aspiration Pneumonitis

The use of VARIBAR PRODUCTS is contraindicated in patients with trachea-esophageal fistula. Oral administration of barium is associated with aspiration pneumonitis, especially in patients with a history of food aspiration or with compromised swallowing mechanism. Vomiting following oral administration of barium sulfate may lead to aspiration pneumonitis. In patients at risk for aspiration, begin the procedure with a small ingested volume of VARIBAR PRODUCTS. Monitor the patient closely for aspiration, discontinue administration of VARIBAR PRODUCTS if aspiration is suspected, and monitor for development of aspiration pneumonitis.

Systemic Embolization

Barium sulfate products may occasionally intravasate into the venous drainage of the GI tract and enter the circulation as a “barium embolus” leading to potentially fatal complications which include systemic and pulmonary embolism, disseminated intravascular coagulation, septicemia and prolonged severe hypotension. Although this complication is exceedingly uncommon after oral administration of a barium sulfate suspension, monitor patients for potential intravasation when administering barium sulfate.

ADVERSE REACTIONS

The most common adverse reactions are nausea, vomiting, diarrhea, and abdominal cramping. Serious adverse reactions and fatalities include aspiration pneumonitis, barium sulfate impaction, intestinal perforation with consequent peritonitis and granuloma formation, vasovagal and syncopal episodes.

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.

Please click here for full Prescribing Information for VARIBAR® THIN LIQUID (barium sulfate) oral suspension.

Please click here for full Prescribing Information for VARIBAR® THIN HONEY (barium sulfate) oral suspension.

Please click here for full Prescribing Information for VARIBAR® NECTAR (barium sulfate) oral suspension.

Please click here for full Prescribing Information for VARIBAR® HONEY (barium sulfate) oral suspension.

Please click here for full Prescribing Information for VARIBAR® PUDDING (barium sulfate) oral paste.

VARIBAR is manufactured by E-Z-EM Canada Inc., for E-Z-EM, Inc., a subsidiary of Bracco Diagnostics Inc., Princeton, NJ 08540.

BRACCO

LIFE FROM INSIDE

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UNLOCKING THE
INVISIBLE

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