SPECTRUM MEDICAL IMAGING CO.

BAYER

Radiology is U

Ultravist®
(iopromide) injection
300 | 370 mg Iodine/mL

Your patients,
your image quality,
your Ultravist

Indications and Usage

Intra-arterial Procedures*: Intra-arterial Procedures*: Ultravist® is indicated for: • Cerebral arteriography and peripheral arteriography in adults; • Coronary arteriography and left ventriculography, visceral angiography, and aortography in adults; • Radiographic evaluation of cardiac chambers and related arteries in pediatric patients aged 2 years and older.

Intravenous Procedures*: Ultravist® is indicated for: • Excretory urography in adults and pediatric patients aged 2 years and older; • Contrast Computed Tomography (CT) of the head and body (intrathoracic, intra-abdominal, and retroperitoneal regions) for the evaluation of neoplastic and non-neoplastic lesions in adults and pediatric patients aged 2 years and older; • Contrast mammography to visualize known or suspected lesions of the breast in adults, as an adjunct following mammography and/or ultrasound.

*Specific concentrations and presentations of Ultravist® are recommended for each type of imaging procedure [see Dosage and Administration (2.2, 2.3, 2.4) in the Full Prescribing Information].

IMPORTANT SAFETY INFORMATION

WARNING: RISK ASSOCIATED WITH INTRATHECAL USE

Intrathecal administration, even if inadvertent, may cause death, convulsions, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, seizures, rhabdomyolysis, hyperthermia, and brain edema.
Ultravist® is not approved for intrathecal use.

Risks Associated with Intrathecal Use: 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. Ultravist® is for intra-arterial or intravenous use only. Ultravist® is not approved for intrathecal use.

Please see additional Important Safety Information throughout this brochure.
Please see Full Prescribing Information for Ultravist®.

A Combination of Experience and Versatility for Today's Radiology Practice

Safety

Studied in clinical trials

Efficacy

- Visualization rated good to excellent in 97%–99% of Phase III Clinical Trial patients. Assessment was based on global evaluation of radiograph quality by rating visualization as excellent, good, poor, or no image for six intra-arterial and three intravenous procedures among 741 patients.[1]
- Lesion visualization using Contrast Enhanced Mammography was evaluated in a published prospective study of 216 women. A total of 226 lesions were evaluated, including 98 (43%) malignant lesions, on a 4-point visualization scale of negative, none, moderate and intense.[1]

Experience

- Used in more than 100 countries worldwide[2]
- 40 years on the global market - first launched in 1985

Versatility

With multiple concentrations and packaging to support today's imaging applications[1]

Nonionic > | **Low osmolar >** | **Iodinated contrast >**

Important Safety Information (continued)

Hypersensitivity Reactions: Ultravist® 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 reaction to a contrast agent and known allergic disorders, or other hypersensitivities. Premedication with antihistamines or corticosteroids does not prevent serious life-threatening reactions but may reduce both their incidence and severity. Obtain a history of allergy, hypersensitivity, or hypersensitivity reactions to iodinated contrast agents and have emergency resuscitation equipment and trained personnel available prior to Ultravist® administration. Monitor all patients for hypersensitivity reactions.

Acute Kidney Injury: AAcute kidney injury, including renal failure, may occur after 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 paraproteinemia, and repetitive and/or large doses of Ultravist® . Use the lowest necessary dose of Ultravist® in patients with renal impairment. Hydrate patients prior to and following Ultravist® administration. Do not use laxatives, diuretics, or preparatory dehydration prior to Ultravist® administration.

Please see additional Important Safety Information throughout this brochure.

Broad Range of Indications for Use in Conventional Radiology, Angiography, and Computed Tomography

Indications and Usage

Intra-arterial Procedures in Adults

Concentration	Indication
300 mg Iodine/mL*	Cerebral arteriography Peripheral arteriography
370 mg Iodine/mL*	Coronary arteriography Left ventriculography Visceral angiography Aortography

***Use single-dose vials.**

Intravenous Procedures in Adults

Concentration	Indication
300 mg Iodine/mL*	Excretory urography
300 mg Iodine/mL‡ **or** **370 mg Iodine/mL‡**	Contrast Computed Tomography (CT) of the head and body (intrathoracic, intra-abdominal, and retroperitoneal regions) for the evaluation of neoplastic and non-neoplastic lesions in adults. Contrast mammography to visualize known or suspected lesions of the breast in adults, as an adjunct following mammography and/or ultrasound.

***Use single-dose vials.**
‡Use single-dose vials or imaging bulk package.

Intra-arterial Procedure in Pediatric Patients ages 2 and older

Concentration	Indication
370 mg Iodine/mL*	Radiographic evaluation of Cardiac Chambers and Related Arteries.

***Use single-dose vials.**

Intravenous Procedures in Pediatric patients ages 2 and older

Concentration	Indication
300 mg Iodine/mL*	Excretory Urography
300 mg Iodine/mL‡	Contrast Computerized Tomography (CT) of the head and body (intrathoracic, intra-abdominal, and retroperitoneal regions) for the evaluation of neoplastic and non-neoplastic lesions in adults and pediatric patients aged 2 years and older

***Use single-dose vials.**
‡Use single-dose vials or imaging bulk package.

Important Safety Information (continued)

Cardiovascular Adverse Reactions: Acute or delayed hemodynamic disturbances may occur in patients with congestive heart failure (CHF), severe renal dysfunction, combined renal and hepatic disease, or combined renal and cardiac disease, particularly with repetitive and/or large doses. Fatal cardiovascular reactions have occurred mostly within 10 minutes of Ultravist® injection; 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 Ultravist® in patients with CHF. Always have emergency resuscitation equipment and trained personnel available. Monitor all patients for severe cardiovascular reactions.

Please see additional Important Safety Information throughout this brochure.

Two Concentrations and Multiple Presentations for Increased Flexibility

	Presentation	
Concentration	**Vial**	**Imaging Bulk Package now available!**
300 mg Iodine/mL	50 mL 100 mL 150 mL	200 mL 500 mL
370 mg Iodine/mL	50 mL 100 mL 150 mL	200 mL 500 mL

Ultravist® is produced in Germany.

Imaging Bulk Packaging Enables Customization

- Multiple contrast exams from a single bottle, with 10-hour post-puncture stand time
- Can help reduce contrast waste compared to single dose vials
- ULTRAVIST IBP is for use only with an automated contrast injection system, contrast management system, or contrast media transfer set approved or cleared for use with Ultravist IBP
- The IBP is to be used in a room designated for radiological procedures that involve intravascular administration of a contrast agent

Important Safety Information (continued)

Thromboembolic Events: Serious, in some cases fatal, thromboembolic events causing myocardial infarction and stroke can occur during angiography procedures. During these procedures, increased thrombosis and activation of the complement system can occur. Risk of thromboembolic events can be influenced by: length of procedure, catheter and syringe material, underlying disease state, and concomitant medications. To decrease 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 the risk of clotting. Avoid angiography in patients with homocystinuria because of the risk of inducing thrombosis and embolism.

Extravasation and Injection Site Reactions: Extravasation can occur, particularly in patients with severe arterial or venous disease. 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.

Please see additional Important Safety Information throughout this brochure.

Ultravist 370: Our Customized Offering to Complement Evolving Clinical Protocols

- Contrast administration timing is an important part of diagnostic efficacy with today's fast-paced multidetector CT scanners[3]
- Ultravist 370 is the one of the most concentrated forms of iodine per mL, allowing the administration of lower contrast volume while maintaining iodine load

Ultravist 370:
The highest iodine concentration currently available

Important Safety Information (continued)

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

Thyroid Dysfunction in Pediatric Patients 0 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 media (ICM) in pediatric patients 0 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 ICM exposure. After exposure to ICM, individualize thyroid function monitoring based on underlying risk factors, especially in term and preterm neonates. The safety and effectiveness of Ultravist® in pediatric patients younger than 2 years of age have not been established, and Ultravist® is not approved for use in pediatric patients younger than 2 years of age.

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

Sickle Cell Crisis in Patients with Sickle Cell Disease: Iodinated contrast agents may promote sickling in individuals who are homozygous for sickle cell disease. Hydrate patients prior to and following 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 contrast agent; prophylactic medications may not prevent or mitigate severe cutaneous adverse reactions. Avoid administering Ultravist® to patients with a history of a severe cutaneous adverse reaction to Ultravist®.

Interference with Laboratory Tests: Ultravist® can interfere with protein-bound iodine test.

Common Adverse Reactions: Common adverse reactions (>1%) are headache, nausea, injection site and infusion site reactions, vasodilatation, vomiting, back pain, urinary urgency, chest pain, pain, dysgeusia, and abnormal vision.

Please see additional Important Safety Information throughout this brochure.

Expanding the Tools That Support Clinical Imaging

From our history of first-to-market products to our on-going research, Bayer continuously invests in new technology to help meet the needs of the imaging community.

- Developed the first MR power injector in the U.S.
- Developed the first CT power injector in the U.S.
- Developed the first PET FDG infusion system in the U.S.
- Developed a connectivity platform
- Developed a multi-patient CT Injection System

Ultravist® (iopromide) Injection: An Integral Part of Our CT Portfolio

Bayer has a history deeply entrenched in contrast, injectors, and informatics. We utilize this knowledge to shape the quality of each product.

Ultravist®

Radiology is U

Your patients, your image quality, your Ultravist

MEDRAD® Centargo CT Injection System

Allowing you to
DO LESS.
Enabling you to
CARE MORE.

High-throughput performance with automated workflows

MEDRAD® Stellant FLEX CT Injection System

Intelligent, Intuitive, Innovative

Versatility for flexible workflows

Cortenic® Connectivity Platform

Unlock the Connected Future

Powered by Cortenic™ Connectivity

Please see Boxed Warning and additional Important Safety Information for Ultravist® throughout this brochure.

Note: The Bayer Radiology contrast and device products should be used in accordance with the Prescribing Information and Instructions for Use, respectively.

References:

1. Ultravist [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals; 2023.

2. Bayer data on file.

3. Bae KT. Intravenous contrast medium administration and scan timing at CT: Considerations and timing. Radiol. 2010;256(1):32-61.

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SPECTRUM MEDICAL IMAGING CO.

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