Indications and Usage

Ultravist® (iopromide) injection is an iodinated contrast agent indicated for:

**Intra-arterial Procedures**: 300 mg Iodine per mL for cerebral arteriography and peripheral arteriography; 370 mg Iodine per mL for coronary arteriography and left ventriculography, visceral angiography, and aortography.

**Intravenous Procedures**: 240 mg Iodine per mL for peripheral venography; 300 mg Iodine per mL for excretory urography; 300 mg Iodine per mL and 370 mg Iodine per mL for contrast Computed Tomography (CT) of the head and body (intrathoracic, intraabdominal and retroperitoneal regions) for the evaluation of neoplastic and non-neoplastic lesions. The usefulness of contrast enhancement for the investigation of the retrobulbar space and of low grade or infiltrative glioma has not been demonstrated.

* For information on the concentrations and doses for the Pediatric Population [see Dosage and Administration (2.3) and Use in Specific Populations (8.4) in the Full Prescribing Information].

Important Safety Information

**WARNING: NOT FOR INTRATHECAL USE**

Inadvertent intrathecal administration may cause death, convulsions, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, seizures, rhabdomyolysis, hyperthermia, and brain edema.

Please see additional Important Safety Information throughout this piece.

Please click here to see the Ultravist® Full Prescribing Information (Vials and Syringes).

Please click here to see the Ultravist® Full Prescribing Information (Pharmacy Bulk Package).

Learn more about Ultravist at ultravist.com
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%
  - Assessment was based on global evaluation of radiograph quality by rating visualization as excellent, good, poor, or no image for five intra-arterial and three intravenous procedures among 708 patients

**Experience**
- Used in more than 120 countries worldwide
- Over 13 million vials sold in 2015

**Versatility**
- With a wide range of concentrations and packaging to support today's imaging applications

**Important Safety Information (continued)**

**Contraindications:** Ultravist® injection is contraindicated for intrathecal use.

Preparatory dehydration (e.g. prolonged fasting and the administration of a laxative before Ultravist® injection) is contraindicated in pediatric patients because of risk of renal failure.

**Anaphylactoid Reactions:** Life-threatening or fatal anaphylactoid reactions may occur during or after Ultravist® administration, particularly in patients with allergic disorders. Increased risk is associated with a history of previous reaction to a contrast agent, a known sensitivity to iodine and known allergic disorders or other hypersensitivities. Exercise extreme caution when considering the use of iodinated contrast agents in patients with these histories or disorders. Emergency facilities and personnel trained in the treatment of anaphylactoid reactions should be available for at least 30 to 60 minutes after Ultravist® administration.

*Please see additional Important Safety Information throughout this piece.*

---

**Indications and Usage**

<table>
<thead>
<tr>
<th>Concentration</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>300 mg Iodine/mL</td>
<td>Cerebral arteriography</td>
</tr>
<tr>
<td>370 mg Iodine/mL</td>
<td>Coronary arteriography</td>
</tr>
<tr>
<td>370 mg Iodine/mL</td>
<td>Coronary arteriography</td>
</tr>
<tr>
<td>300 mg Iodine/mL</td>
<td>Left ventriculography</td>
</tr>
<tr>
<td>or 370 mg Iodine/mL</td>
<td>Visceral angiography</td>
</tr>
<tr>
<td></td>
<td>Aortography</td>
</tr>
</tbody>
</table>

**Intravenous Procedures in Adults**

<table>
<thead>
<tr>
<th>Concentration</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>240 mg Iodine/mL</td>
<td>Peripheral venography</td>
</tr>
<tr>
<td>300 mg Iodine/mL</td>
<td>Excretory urography</td>
</tr>
<tr>
<td>300 mg Iodine/mL or 370 mg Iodine/mL</td>
<td>Contrast Computed Tomography (CT) of the head and body (intrathoracic, intraabdominal and retroperitoneal regions) for the evaluation of neoplastic and non-neoplastic lesions. The usefulness of contrast enhancement for the investigation of the retrobulbar space and of low grade or infiltrative glioma has not been demonstrated.</td>
</tr>
</tbody>
</table>

*For information on the concentrations and doses for the Pediatric Population [see Dosage and Administration (2.3) and Use in Specific Populations (8.4) in the Full Prescribing Information].

**Important Safety Information (continued)**

**Contrast Induced Acute Kidney Injury:** Acute kidney injury, including renal failure, may occur after intravascular administration of Ultravist®. 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/paraproteinemia, repetitive and/or large doses of Ultravist®. Use the lowest necessary dose of Ultravist® in patients with renal impairment. Adequately hydrate patients prior to and following Ultravist® administration.

*Please see additional Important Safety Information throughout this piece.*

---

**Nonionic**  ✔
**Low osmolar**  ✔
**Iodinated contrast**  ✔
Diverse Concentrations and Presentations for Increased Flexibility

<table>
<thead>
<tr>
<th>Concentration</th>
<th>Vial</th>
<th>Pharmacy Bulk Package</th>
</tr>
</thead>
<tbody>
<tr>
<td>240 mg Iodine/mL</td>
<td>100 mL</td>
<td>200 mL</td>
</tr>
<tr>
<td>300 mg Iodine/mL</td>
<td>50 mL</td>
<td>200 mL</td>
</tr>
<tr>
<td></td>
<td>100 mL</td>
<td>500 mL</td>
</tr>
<tr>
<td></td>
<td>125 mL</td>
<td></td>
</tr>
<tr>
<td></td>
<td>150 mL</td>
<td></td>
</tr>
<tr>
<td>370 mg Iodine/mL</td>
<td>50 mL</td>
<td>250 mL</td>
</tr>
<tr>
<td></td>
<td>100 mL</td>
<td>500 mL</td>
</tr>
<tr>
<td></td>
<td>150 mL</td>
<td></td>
</tr>
<tr>
<td></td>
<td>200 mL</td>
<td></td>
</tr>
</tbody>
</table>

Pharmacy Bulk Packaging Enables Customization and Efficiency
- Custom dosing for each patient, equipment type, and procedure
- Multiple contrast exams from a single bottle, with 10-hour post-puncture stand time
- Reduced contrast waste

Important Safety Information (continued)
Cardiovascular Reactions: Hemodynamic disturbances including shock and cardiac arrest may occur during or shortly after administration of Ultravist®. Observe patients with preexisting cardiovascular disease for several hours following Ultravist® administration.

Thromboembolic Complications: Angiography may be associated with local and distal organ damage, ischemia, thromboembolism and organ failure. In angiographic procedures, consider the possibility of dislodging plaques or damaging or perforating the vessel wall. The physicochemical properties of the contrast agent, the dose and the speed of injection can influence the reactions. Monitor electrocardiograms and vital signs throughout the procedure. Exercise care when performing venography in patients with suspected thrombosis, phlebitis, severe ischemic disease, local infection, venous thrombosis or a totally obstructed venous system. Clotting may occur when blood remains in contact with syringes containing iodinated contrast agents. Avoid angiography whenever possible in patients with homocystinuria because of the risk of inducing thrombosis and embolism.

Please see additional Important Safety Information throughout this piece.

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
- Ultravist 370 is the most concentrated form of iodine per mL, allowing the administration of lower contrast volume while maintaining iodine load

Ultravist 370 is indicated for:
- **Intra-arterial Procedures:** 370 mg iodine per mL for coronary arteriography and left ventriculography, visceral angiography, and aortography.
- **Intravenous Procedures:** 370 mg iodine per mL for contrast Computed Tomography (CT) of the head and body (intrathoracic, intraabdominal and retroperitoneal regions) for the evaluation of neoplastic and non-neoplastic lesions. The usefulness of contrast enhancement for the investigation of the retrobulbar space and of low grade or infiltrative glioma has not been demonstrated.

Important Safety Information (continued)
Reactions in Patients with Hyperthyroidism, Pheochromocytoma, or Sickle Cell Disease:
Thyroid storm has occurred after the intravascular use of iodinated contrast agents in patients with hyperthyroidism, or with autonomously functioning thyroid nodule. Evaluate the risk in such patients before use of any iodinated contrast agent. Administer iodinated contrast agents with extreme caution in patients with known or suspected pheochromocytoma. Inject the minimal amount of contrast necessary. Contrast agents may promote sickling in individuals who are homozygous for sickle cell disease when administered intravascularly.

Please see additional Important Safety Information throughout this piece.
Committed to Access and Quality...

Uninterrupted access and high-quality supply are more important than ever.

The synthesis and formulation of Ultravist require expert knowledge and advanced technology. Bayer invests in production sites to support availability and adherence to quality standards at every step, including:

- Establishment of additional Ultravist production line in Bergkamen, Germany to address increasing worldwide demand and maintain consistent supply
- Compliance with Good Manufacturing Practices (GMP)

Important Safety Information (continued)

Extravasation: Extravasation of Ultravist® may cause tissue necrosis and/or compartment syndrome, particularly in patients with severe arterial or venous disease.

Increased Radiation Exposure: The decision to use contrast enhancement is associated with risk and increased radiation exposure.

Please see additional Important Safety Information throughout this piece.

...and 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.
- Pioneered development in Radiation Dose and Contrast Dose Management informatics with consistent software upgrades every year
- Developed the first PET FDG infusion system in the U.S.

Important Safety Information (continued)

Interference with Image Interpretation: The use of Ultravist® Injection may obscure some lesions which were seen on non-contrast CT scans. Calcified lesions are less likely to enhance. The enhancement of tumors after therapy may decrease. The specification of the inferior vermis following contrast agent administration has resulted in false-positive diagnosis. Cerebral infarctions of recent onset may be better visualized with contrast enhancement. However, older infarctions may be obscured by the contrast agent. In patients with normal blood-brain barriers and renal failure, iodinated contrast agents have been associated with blood-brain barrier disruption and accumulation of contrast in the brain. Accumulation of contrast in the brain also occurs in patients where the blood-brain barrier is known or suspected to be disrupted.

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®.

Please see additional Important Safety Information throughout this piece.

Ultravist®
(iopromide) injection
240 | 300 | 370 mg/mL
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® (iopromide) injection
240 | 300 | 370 mg I/mL

Radiology is U
Your patients, your image quality, your Ultravist®

Intelligent, Intuitive, Innovative
Confidence Through Patient-centered Care and Efficiency

Remote Service Technology
Enables Advanced Diagnostics and Real-time Support

Seamlessly Smart

* Ultravist should be used in accordance with the FDA-approved label

Important Safety Information (continued)

Most Common Adverse Reactions: Most 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 piece.


Bayer Pharmaceuticals Division
Bayer HealthCare LLC
100 Bayer Boulevard
P.O. Box 915
Whippany, NJ 07981
www.radiologysolutions.bayer.com

Bayer Medical Care Inc.
1 Bayer Drive
Indianola, PA 15051 USA
Customer Service/Orders
1-800-633-7231
Customer Service Fax
1-412-767-4120

Bayer reserves the right to modify the specifications and features described herein, or discontinue manufacture of the product described at any time without prior notice or obligation. Please contact your authorized Bayer representative for the most current information. Bayer, the Bayer Cross, Ultravist®, Medrad®, Stellant®, VirtualCare®, and Radimetrics™ are trademarks of the Bayer group of companies.

PP-346-US-0064 July 2017