SPECTRUM MEDICAL IMAGING CO.

BAYER

Ultravist® Imaging Bulk Package

Now available: 200 and 500 mL Ultravist® IBP Bottles

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

To streamline workflow, especially in busier CT radiology suites, Ultravist® is now available in an Imaging Bulk Package (IBP) in two concentrations – 300 and 370 mg Iodine/mL and two sizes – 200 and 500 mL bottles.

Is intended to be used in a room designated for radiological procedures that involve intravascular administration of a contrast agent.

Indications and Usage

ULTRAVIST Imaging Bulk Package is indicated for:

- 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 2.3, 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® Imaging Bulk Package is for 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®.

Now available in an IBP in two concentrations – 300 and 370 mg Iodine/mL and two sizes – 200 and 500 mL bottles.

1 bottle, 1 spike, multiple patients: With 10-hour stand-time after intitial spike, the same bottle can be used across multiple patient scans and staff shifts.

- 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

Convenience: The larger size means that you can conduct more scans per bottle, and need fewer bottle changes, as compared to single-dose vials.

Two bottle sizes available: Choose the most efficient solution for your suite – with a choice of two bottle sizes.

Reduced Waste: The Imaging Bulk Package may enable more complete contrast usage compared to single-dose vials.

Important Safety Information (continued)

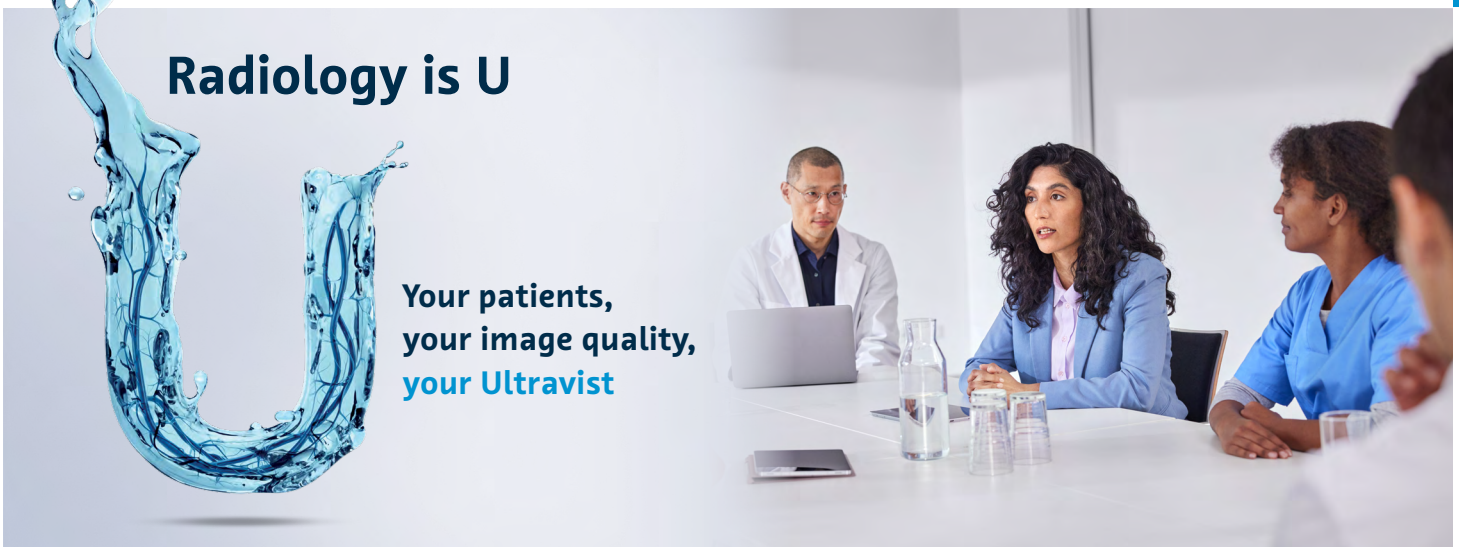
Hypersensitivity Reactions: Ultravist® can cause life-threatening or fatal hypersensitivity reactions including anaphylaxis. Manifestations include respiratory arrest, laryngospasm, bronchospasm, angioedema, and shock. Most severe reactions develop shortly after the start of injection (e.g., within 1 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: Acute 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.

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. 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.

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.



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.

Streamline workflow, and redirect time to patient care with MEDRAD® Centargo CT Injection System

The integrated barcode reader can save time by automatically capturing key data from the bottle, reducing manual data entry.

Centargo gives you the flexibility to use Ultravist® contrast in an Imaging Bulk Package (IBP) presentation.

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