ULTRAVIST Abridged Prescribing Information :
For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

Composition : Ultravist 300: 1 ml contains 0.623 g Iopromide USP (equivalent to 300 mg Iodine), Ultravist 370: 1 ml contains 0.769 g Iopromide USP (equivalent to 370 mg Iodine)**Indications**: This medicinal product is for diagnostic use only. To be used as a contrast medium for Uro-angiography, for intravascular use & use in body cavities for contrast enhancement in Computerized Tomography (CT), arteriography and venography, intravenous/ intraarterial digital subtraction angiography (DSA), intravenous urography, use for ERCP, arthrography and examination of other body cavities. **Dosage and method of administration:** *For intravascular use:* Dosage should be adapted to age, weight, clinical question and examination technique. Generally, doses of up to 1.5 g iodine per kg body weight are well tolerated, *for use in body cavities:* Arthrography: 5 - 15 ml Ultravist 300/370**,** ERCP: Dosage depends generally on clinical question and size of structure to be imaged. Other: Dosage depends generally on clinical question and size of structure to be imaged. **Additional Information on special population: Newborns (< 1 month) and infants (1 month -2 years):** Young infants (age < 1 year) and especially newborns are susceptible to electrolyte imbalance and hemodynamic alterations. Care should be taken regarding the dose of contrast medium to be given, the technical performance of the radiological procedure and the patient status**. Elderly population (aged 65 years and above**): no specific recommendation for a dosage adjustment is given for elderly patients. **Patients with hepatic impairment:** No dosage adjustment is considered necessary in patients with hepatic impairment. **Patients with renal impairment:** In order to reduce the risk of additional contrast media-induced renal impairment in patients with pre-existing renal impairment, the minimum possible dose should be used in these patients. **Contraindications**: There are no absolute contraindications to the use of Ultravist. **Special warnings and special precautions**: Caution is advised in patients with hypersensitivity or a previous reaction, bronchial asthma, thyroid dysfunction, CNS disorders, anxiety, renal impairment, cardiovascular disease, pheochromocytoma, myasthenia gravis and thromboembolic events. Adequate hydration status must be assured in renally impaired patients) **Drugs Interactions:** Patients treated with metformin may be at an increased risk of developing lactic acidosis, especially those with prior renal impairment. Previous treatment with Interleukin-2 is associated with an increased risk for delayed reactions to Ultravist. Diagnosis and treatment of thyroid disorders with radioisotopes maybe impeded after administration of Ultravist due to reduced uptake. **Undesirable effects**: *Immune system disorders:* (uncommon)- Hypersensitivity / anaphylactoid reactions such as: anaphylactoid shock, respiratory arrest, bronchospasm- laryngeal / pharyngeal, face edema, tongue edema, laryngeal / pharyngeal spasm, asthma , conjunctivitis, lacrimation, sneezing, cough, mucosal edema, rhinitis, hoarseness, throat irritation, urticaria, pruritus, angioedema; *Endocrine disorders:* (not known)- Thyrotoxic crisis, Thyroid disorder; *Psychiatric disorders*: (Rare)- Anxiety; *Nervous system disorders:* (Common)- Dizziness, Headache, Dysgeusia; (uncommon)- Vasovagal reactions, Confusional state, Restlessness, Paresthesia / hypoesthesia, Somnolence; (not known)- Coma, Cerebral ischemia / infarction, Stroke, Brain edema, Convulsion, Transient cortical blindness, Loss of consciousness, Agitation, Amnesia, Tremor, Speech disorders, Paresis / paralysis; *Eye disorders:* (Common)- Blurred/ disturbed vision; *Ear and labyrinth Disorders:* (not known)- Hearing disorders; *Cardiac disorders:* (common)- Chest pain / discomfort; (uncommon)- Arrhythmia; (rare)- Cardiac arrest, Myocardial ischemia, Palpitations; (not known)- Myocardial infarction, Cardiac failure, Bradycardia, Tachycardia, Cyanosis; *Vascular disorders:* (common)-Hypertension, Vasodilatation; (uncommon)- Hypotension; (not known)- Shock, Thromboembolic events, Vasospasm, *Respiratory, thoracic and mediastinal disorders:* (uncommon)- Dyspnea; (not known)- Pulmonary edema, Respiratory insufficiency, Aspiration; *Gastrointestinal disorders:* (common)- Vomiting, Nausea; (uncommon)- Abdominal pain; (not known)- Dysphagia, Salivary

gland enlargement, Diarrhea; *Skin and subcutaneous tissue disorders*: (Not known)- Severe cutaneous reactions: Toxic epidermal reactions: Toxic epidermal necrolysis (TEN)/Lyell syndrome, Stevens-Johnson syndrome (SJS), Drug reaction with eosinophilia and systemic symptoms (DRESS), Acute generalized exanthematous pustulosis (AGEP) Rash, Erythema, Hyperhydrosis; *Musculoskeletal, connective tissue and bone disorders:* (not known)- Compartment syndrome in case of extravasation; *Renal and urinary disorders:* (not known)- Renal impairment, Acute renal failure, *General disorders and administration site conditions:* (common)- Pain, Injection site reactions like pain, warmth, inflammation and soft tissue injury in case of extravasation), Feeling hot; (uncommon)- Edema; (not known)- Malaise, Chills, Pallor; *Investigations:* (not known)- Body temperature fluctuation. Elevation of pancreatic enzyme levels and pancreatitis at an unknown frequency have been reported with use for ERCP. **Overdose:** *Intravascular overdose*: Symptoms may include fluid and electrolyte imbalance, renal failure, cardiovascular and pulmonary complications. In case of inadvertent intravascular over dosage, it is recommended to monitor fluids, electrolytes, and renal function. Ultravist is dialyzable. **Storage and handing instructions:** Ultravist should be warmed to body temperature prior to use. Protect from light and secondary X-rays. Store below 30°C. Keep out of reach of children. Contrast media should be visually inspected prior to use and must not be used, if discolored, nor in the presence of particulate matter (including crystals) or defective containers. For large volume containers: The contrast medium must be administered by means of an automatic injector, or by other approved procedures which ensure sterility of the contrast medium. Instructions of the device manufacturer must be followed. Unused Ultravist in opened containers must be discarded ten hours after first opening the container.. Please refer to full prescribing information before use. **Source:** PI Version No. UL_2022_01 dated 22 Dec 2022. Based on CCDS version 18 dated Aug 01, 2022 & US PI dated Feb 2022, **Date of API update:** 25-09-2024.