1. NAME OF THE MEDICINAL PRODUCT

Ultravist 300/370, solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ultravist 300: 1ml contains 623 mg iopromide (equivalent to 300 mg iodine)
Ultravist 370: 1ml contains 769 mg iopromide (equivalent to 370 mg iodine)

For a full list of excipients, see section 'List of excipients'.

3. PHARMACEUTICAL FORM

Solution for injection

Clear, very slightly brown, very slightly brownish-yellow or very slightly yellow solution.

The physico-chemical properties of Ultravist at the concentrations listed below are:

Iodine concentration (mg/ml)	300	370
Osmolality (osm/kg H_2O) at 37^0C	0.61	0.77
Viscosity (mPa.s) at 20^0C at 37^0C	 8.7 4.6	 20.1 9.5
Density (g/ml) at 20^0C at 37^0C	 1.328 1.322	 1.409 1.399
pH-value	6.5 – 8.0	6.5 – 8.0

4. CLINICAL PARTICULARS

4.1 Indications

This medicinal product is for diagnostic use only.

Ultravist 300:
Contrast enhancement in computerized tomography (CT), digital subtraction angiography (DSA), intravenous urography, phlebography of the extremities, venography, arteriography, visualization of body cavities (e.g. arthrography, hysterosalpingography, fistulography) **with the exception of myelography, ventriculography, cisternography.**

Ultravist 370:
Contrast enhancement in computerized tomography (CT), digital subtraction angiography (DSA), intravenous urography, arteriography and especially angiocardiography, visualization of body cavities (e.g. arthrography, fistulography) **with the exception of myelography, ventriculography, cisternography.**

4.2 Dosage and method of administration

4.2.1 General information

Contrast media which are warmed to body temperature before administration are better tolerated and can be injected more easily because of reduced viscosity.

For additional instructions, see section ‘Instructions for use/handling’.

4.2.2 Dosage regimen

Intravenous urography

Adults
The dose should not be less than 1 ml Ultravist 300 (0.8 ml Ultravist 370)/kg body weight if the clinical problem also requires adequate filling of the ureters. Increasing the dose is possible if this is considered necessary in special indications.

Children
The physiologically poor concentrating ability of the still immature nephron of infantile kidneys demands relatively high doses of contrast medium, e.g. with the use of Ultravist 300:
Neonates: 1.2 g I/kg body weight, corresponding to 4.0 ml/kg body weight
Babies: 1.0 g I/kg body weight, corresponding to about 3.0 ml/kg body weight
Small children: 0.5 g I/kg body weight, corresponding to about 1.5 ml/kg body weight

Filming times
When the above dosage guidelines are observed and Ultravist 300/370 is injected over 1 to 2 minutes, the renal parenchyma is usually highly opacified 3 to 5 minutes and the renal pelvis with the urinary tract 8 to 15 minutes after the start of administration. The earlier time should be chosen for younger patients and the later time for older patients.

In babies and young children it is advisable to take the first film as early as about 2 minutes after the administration of the contrast medium. Insufficient contrast can necessitate later films.

Computerized tomography (CT)

Whole-body CT
In whole-body computerized tomography, the necessary doses of contrast medium and the rates of administration depend on the organs under investigation, the diagnostic problem and, in particular, the different scan and image reconstruction times of the scanners in use. The infusion should be preferred for slow scanners and the injection as a bolus for fast scanners.

Cranial CT

The following dosages are recommended for cranial CT:
Ultravist 300: 1.0 – max. 2.0 ml/kg body weight

Ultravist 370: 1.0 – max. 1.5 ml/kg body weight

Conventional Angiography

Recommended doses for single injections:

Cerebral angiography
Aortic arch angiography 50 – 80ml Ultravist 300
Retrograde carotid
Angiography 30 – 40ml Ultravist 300
Selective angiography 6 – 15 ml Ultravist 300

Thoracic aortography 50 – 80 ml Ultravist 300

Abdominal aortography 40 – 60 ml Ultravist 300

Angiography of the extremities
Upper extremities:
Arteriography 8 – 12 ml Ultravist 300
Venography 15 – 30 ml Ultravist 300

Lower extremities:
Arteriography 20 – 30 ml Ultravist 300
Venography 30 – 60 ml Ultravist 300

Angiocardiography
Selective, in the individual cardiac cavities: 40 –60ml Ultravist 370

Coronary angiography 5 – 8ml Ultravist 370

Intravenous Digital subtraction angiography (DSA)

The i.v. injection of 30 – 60 ml Ultravist 300 or 370 as a bolus (flow rate: 8 – 12 ml/second into the cubital vein; 10 – 20 ml/second into the vena cava) is only recommended for contrast demonstrations of great vessels of the trunc. The amount of contrast medium remaining in the veins can be reduced and diagnostically used by flushing with isotonic sodium chloride solution as a bolus immediately afterwards.

Adults: 30 – 60 ml Ultravist 300/370

4.2.3 Additional information on special populations

4.2.3.1 Newborns (< 1 month) and infants (1 month – 2 years)

Young infants (age <1 years) 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.

4.2.3.2 Patients with renal impairment

Since iopromide is excreted almost exclusively in an unchanged form via the kidneys, the elimination of iopromide is prolonged in patients with renal impairment. In order to reduce the risk of additional contrast media-induced kidney injury in patients with pre-existing renal impairment, the minimum possible dose should be used in these patients (see also sections ‘Special warnings and precautions for use’ and ‘Pharmacokinetic properties’).

4.3 Contraindications

There are no absolute contraindications to the use of Ultravist.

4.4 Special warnings and special precautions for use

4.4.1 For all indications

4.4.1.1 Hypersensitivity reactions

Ultravist can be associated with anaphylactoid/ hypersensitivity or other idiosyncratic reactions characterized by cardiovascular, respiratory and cutaneous manifestations.

Allergy-like reactions ranging from mild to severe reactions including shock are possible (see section ‘Undesirable effects’). Most of these reactions occur within 30 minutes of administration. However, delayed reactions (after hours to days) may occur.

The risk of hypersensitivity reactions is higher in case of:
- previous reaction to contrast media
- history of bronchial asthma or other allergic disorders.

Particularly careful risk/benefit judgment is required in patients with known hypersensitivity to Ultravist or any excipient of Ultravist, or with a previous hypersensitivity reaction to any other iodinated contrast medium due to an increased risk for hypersensitivity reactions (including severe reactions). However, such reactions are irregular and unpredictable in nature. Hypersensitivity reactions can be aggravated in patients on beta blockers, particularly in patients with bronchial asthma. Patients who experience such reactions while taking beta blockers may be resistant to treatment effects of beta agonists.

In the event of a severe hypersensitivity reaction, patients with cardiovascular disease are more susceptible to serious or even fatal outcomes.

Due to the possibility of severe hypersensitivity reactions after administration, post-procedure observation of the patient is recommended.

Preparedness for institution of emergency measures is necessary for all patients.

In patients with an increased risk of acute allergy-like reactions, patients with a previous moderate or severe acute reaction, asthma or allergy requiring medical

treatment, premedication with a corticosteroid regimen may be considered.

4.4.1.2 Thyroid dysfunction

Ultravist like all other iodinated contrast media, may induce changes in thyroid function in some patients. Transient hyperthyroidism or hypothyroidism has been reported following iodinated contrast media administration to adults and paediatric patients.

Decreased levels of thyroxine (T4) and triiodothyronine (T3) and increased level of TSH were reported after exposure to iodinated contrast media in infants, especially preterm infants, which remained for up to a few weeks or more than a month (see ADVERSE REACTIONS). Hypothyroidism in infants may be harmful for growth or development, including mental development, and may require treatment. Thyroid function in infants exposed to iodinated contrast media should therefore be evaluated and monitored until thyroid function is normalised.

Particularly careful risk/benefit judgment is required in patients with known or suspected hyperthyroidism or goitre, as iodinated contrast media may induce hyperthyroidism and thyreotoxic crisis in these patients. Testing of thyroid function prior to Ultravist administration and/or preventive thyreostatic medication may be considered in patients with known or suspected hyperthyroidism.

Thyroid function tests indicative of hypothyroidism or transient thyroid suppression have been reported following iodinated contrast media administration to adult and pediatric patients. Evaluate the potential risk of hypothyroidism in patients with known or suspected thyroid diseases before use of iodinated contrast media.

In neonates, specially preterm infants, who have been exposed to Ultravist, either through the mother during pregnancy or in the neonatal period, it is recommended to monitor thyroid function, as an exposure to excess iodine may cause hypothyroidism, possibly requiring treatment.

4.4.1.3 CNS disorders

Patients with CNS disorders may be at increased risk to have neurological complications in relationship to Ultravist administration. Neurological complications are more frequent in cerebral angiography and related procedures.

Caution should be exercised in situations in which there may be a reduced seizure threshold, such as a previous history of seizures and the use of certain concomitant medication.

Factors which increase blood-brain barrier permeability facilitate the passage of the contrast medium into cerebral tissue, possibly leading to CNS reactions.

4.4.1.4 Hydration

Adequate hydration status must be assured in all patients before intravascular or intrathecal Ultravist administration in order to minimize the risk of contrast media-induced nephrotoxicity (see also subsection – ‘4.4.2.1 Acute Kidney Injury’).

This applies especially to patients with multiple myeloma, diabetes mellitus, polyuria, oliguria, hyperuricemia, as well as to newborns, infants, small children and elderly patients.
Adequate hydration status must be assured in renally impaired patients. However, prophylactic IV hydration in patients with moderate renal impairment (eGFR 30-59 mL/min/1.73 m^2) is not recommended as additional renal safety benefits have not been established. In patients with severe renal impairment (eGFR <30 mL/min/1.73 m^2) and concomitant cardiac conditions, prophylactic IV hydration can lead to increased serious cardiac complications. Refer to subsection '4.4.2.1 Acute Kidney Injury', '4.4.2.2 Cardiovascular disease', '4.8.2 Tabulated list of adverse reactions.'

4.4.1.5 Anxiety

Pronounced states of excitement, anxiety and pain may increase the risk of side effects or intensify contrast medium-related reactions. Care should be taken to minimize the state of anxiety in such patients.

4.4.1.6 Pretesting

Sensitivity testing using a small test dose of contrast medium is not recommended as it has no predictive value. Furthermore, sensitivity testing itself has occasionally led to serious and even fatal hypersensitivity reactions.

4.4.2 Intravascular use

4.4.2.1 Acute Kidney Injury

Post-Contrast Acute Kidney Injury (PC-AKI), presenting as a transient impairment of renal function, may occur after intravascular administration of Ultravist. Acute renal failure may occur in some cases.

Risk factors include, e.g.:
-pre-existing renal insufficiency (see subsection '4.2.3.4 Patients with renal impairment'),
-dehydration (see subsection '4.4.1.4 Hydration'),
-diabetes mellitus,
-multiple myeloma/paraproteinemia
-repetitive and/or large doses of Ultravist.

Patients with moderate to severe (eGFR 44-30 mL/min/1.73 m^2) or severe renal impairment (eGFR <30 mL/min/1.73 m^2) are at increased risk of Post-Contrast Acute Kidney Injury (PC-AKI) with intra-arterial contrast administration and first pass renal exposure.
Patients with severe renal impairment (eGFR <30 mL/min/1.73 m^2) are at increased risk of PC-AKI with intra-venous or intra-arterial contrast administration with second pass renal exposure (see subsection '4.4.1.4 Hydration').

Patients on dialysis, if without residual renal function, may receive Ultravist for radiological procedures as iodinated contrast media are cleared by the dialysis process.

4.4.2.2 Cardiovascular disease

Patients with significant cardiac disease or severe coronary artery disease are at an increased risk of developing clinically relevant hemodynamic changes and arrhythmia.

The intravascular injection of Ultravist may precipitate pulmonary edema in patients with heart failure.

4.4.2.3 Pheochromocytoma

Patients with pheochromocytoma may be at increased risk to develop a hypertensive crisis.

Administer iodinated contrast agents with extreme caution in patients with known or suspected of having pheochromocytoma. Inject the minimum amount of contrast necessary. Assess the blood pressure throughout the procedure, and have measures for treatment of a hypertensive crisis readily available.

4.4.2.4 Myasthenia gravis

The administration of iodinated contrast media Ultravist may aggravate the symptoms of myasthenia gravis.

4.4.2.5 Thromboembolic events

A property of non-ionic contrast media is the low interference with normal physiological functions. As a consequence of this, non-ionic contrast media have less anticoagulant activity in vitro than ionic media. Numerous factors in addition to the contrast medium, including length of procedure, number of injections, catheter and syringe material, underlying disease state, and concomitant medication may contribute to the development of thromboembolic events. Therefore, when performing vascular catheterization procedure one should be aware of this and pay meticulous attention to the angiographic technique and flush the catheter frequently with physiological saline (if possible with the addition of heparin) and minimize the length of the procedure so as to minimize the risk of procedure-related thrombosis and embolism.

4.4.3 Intrathecal use

Care is needed in patients with a seizure history due to an increased risk for seizures in relationship to intrathecal Ultravist administration. Preparedness for institution of anti-convulsive measures is recommended.

The majority of adverse reactions after myelography occur some hours after administration. During this period, observation is advisable.

4.5 Interaction with other medicaments and other forms of interaction

Biguanides (metformin): In patients with acute kidney failure or severe chronic kidney disease biguanide elimination can be reduced leading to accumulation and the development of lactic acidosis. As the application of Ultravist can lead to renal

impairment or an aggravation of renal impairment, patients treated with metformin may be at an increased risk of developing lactic acidosis, especially those with prior renal impairment (see section ‘Special warnings and precautions for use’ – subsection ‘Intravascular use’ –Acute Kidney Injury).

Interleukin-2: Previous treatment (up to several weeks) with Interleukin-2 is associated with an increased risk for delayed reactions to Ultravist.

Radioisotopes: Diagnosis and treatment of thyroid disorders with thyrotropic radioisotopes may be impeded for up to several weeks after administration of Ultravist due to reduced radioisotope uptake.

4.6 Pregnancy and lactation

4.6.1 Pregnancy

Adequate and well-controlled studies in pregnant women have not been conducted. It has not been sufficiently demonstrated that non ionic contrast media are safe for use in pregnant patients. Since, wherever possible, radiation exposure should be avoided during pregnancy, the benefits of any X-ray examination, with or without contrast media, should be carefully weighed against the possible risk.

Embryotoxicity including teratogenicity studies have been performed in rats and rabbits at doses up to 3.7 g I/kg body weight. These studies did not indicate an increased risk of adverse effects to the foetus following the intended diagnostic use in humans.

4.6.2 Lactation

Safety of Ultravist for nursed infants has not been investigated. Contrast media are poorly excreted in human breast milk. Harm to nursed infant is not likely (see also section ‘Special warnings and precautions for use’ – subsection ‘Thyroid dysfunction’.

4.7 Effects on ability to drive and use machines

Not known

4.8 Undesirable effects

4.8.1 Summary of safety profile

The overall safety profile of Ultravist is based on data obtained in pre-marketing studies in more than 3900 patients and post-marketing studies in more than 74 000 patients, as well as data from spontaneous reporting and the literature.

The most frequently observed adverse drug reactions (≥ 4%) in patients receiving Ultravist are headache, nausea and vasodilatation.

The most serious adverse drug reactions in patient receiving Ultravist are anaphylactoid shock, respiratory arrest, bronchospasm, laryngeal edema, pharyngeal

edema, asthma, coma, cerebral infarction, stroke, brain edema, convulsion, arrhythmia, cardiac arrest, myocardial ischemia, myocardial infarction, cardiac failure, bradycardia, cyanosis, hypotension, shock, dyspnea, pulmonary edema, respiratory insufficiency and aspiration.

4.8.2 Tabulated list of adverse reactions

The adverse drug reactions observed with Ultravist are represented in the table below. They are classified according to System Organ Class (MedDRA version 13.0). The most appropriate MedDRA term is used to describe a certain reaction and its synonyms and related conditions.

The adverse drug reactions identified only during post-marketing surveillance, and for which a frequency could not be estimated, are listed under 'not known'.

Table: Adverse drug reactions (ADRs) reported in clinical trials or during post-marketing surveillance in patients treated with Ultravist

System organ class	Common (≥1/100 to <1/10)	Uncommon (≥ 1/1,000 to <1/100)	Rare (≥1/10,000 to < 1/1,000)	Not known
Immune system disorders		Hypersensitivity/ Anaphylactoid reactions (anaphylactoid shock[b*], respiratory arrest[b*], bronchospasm[*], laryngeal[*]/ pharyngeal[*]/ face edema, tongue edema[b], laryngeal/ pharyngeal spasm[b], asthma[b*], conjunctivitis, lacrimation[b], sneezing, cough, mucosal edema, rhinitis[b],hoarseness[b], throat irritation[b], urticaria, pruritus, angioedema		
Endocrine disorders[†]				Alteration in thyroid function, thyrotoxic crisis
Psychiatric disorders			Anxiety	

Nervous system disorders	Dizziness, headache, dysgeusia	Vasovagal reactions, confusional state, Restlessness, paraesthesia/ hypoaesthesia, somnolence		Coma*, cerebral ischemia/infarction*, stroke*, brain edema[a]*, convulsion*, transient cortical blindness[a], loss of consciousness, agitation, amnesia, tremor, speech disorders, paresis/paralysis
Eye disorders	Blurred / disturbed vision			
Ear and labyrinth disorders				Hearing disorders
Cardiac disorders	Chest pain/ discomfort	Arrhythmia *	Cardiac arrest*, myocardial ischemia*, Palpitations	Myocardial infarction*, cardiac failure*, bradycardia*, tachycardia, cyanosis*
Vascular disorders	Hypertension, vasodilatation	Hypotension*	,	Shock*, thromboembolic events[a], vasospasm[a]
Respiratory, thoracic and mediastinal disorders		Dyspnea*		Pulmonary edema*, respiratory insufficiency*, aspiration*
Gastrointestinal disorders	Vomiting, nausea	Abdominal pain		Dysphagia, salivary gland enlargement, diarrhoea
Skin and subcutaneous tissue disorders				Severe cutaneous 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				Compartment syndrome in case of extravasation[a]

disorders				
Renal and urinary				Renal impairment[a], acute renal failure[a]
General disorders and administration site conditions	Pain, injection site reactions (various kinds e.g. pain, warmth[b], edema[b], inflammation[b] and soft tissue injury[b] in case of extravasation), feeling hot	Edema		Malaise, chills, pallor
Investigations				Body temperature fluctuation

[*]- Life-threatening and/or fatal cases have been reported
[a]- intravascular use only
[b]- identified only during post-marketing surveillance (frequency not known)
[†] Endocrine Disorders - Thyroid function tests indicative of hypothyroidism or transient thyroid suppression have been uncommonly reported following iodinated contrast media administration to adult and paediatric patients, including infants. Some patients were treated for hypothyroidism.

4.8.3 Description of selected adverse reactions

Based on experience with other non-ionic contrast media, the following undesirable effects may occur with intrathecal use in addition to the undesirable effects listed above:
Psychosis, neuralgia, paraplegia, aseptic meningitis, back pain, pain in extremities, micturition disorder, EEG abnormal.

4.9 Overdose

Results from acute toxicity studies in animals do not indicate a risk of acute intoxication following use of Ultravist.

4.9.1 Intravascular overdose

Symptoms may include fluid and electrolyte imbalance, renal failure, cardiovascular and pulmonary complications.

In case of inadvertent intravascular overdosage, it is recommended to monitor fluids, electrolytes, and renal function. Treatment of overdose should be directed towards the support of vital functions.

Ultravist is dialyzable (see section ‘Pharmacokinetic properties’).

4.9.2 Intrathecal overdose

Serious neurological complications may occur. Close monitoring is recommended in case of inadvertent intrathecal overdosage.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Water-soluble, nephrotropic, low osmolar X-ray contrast media

ATC code: V08AB05

The contrast-giving substance in the Ultravist formulations is iopromide, a non-ionic, water-soluble derivative of triiodinated isophthalic acid with a molecular weight of 791.12, in which the firmly bound iodine absorbs the X-rays.

Injection of iopromide opacifies those vessels or body cavities in the path of flow of the contrast agent, permitting radio-graphic visualization of the internal structures until significant dilution occurs.

5.2 Pharmacokinetic properties

5.2.1 General information

Iopromide behaves in the organism like other highly hydrophilic, biologically inert, renally excreted compounds (e.g. mannitol or inulin).

5.2.2 Absorption and distribution

Following intravenous administration, plasma concentrations of iopromide decline rapidly due to distribution into the extracellular space and subsequent elimination. The total distribution volume at steady state is about 16L corresponding roughly to the volume of the extracellular space.

Plasma protein-binding is negligible (about 1%). There is no indication that iopromide crosses the intact blood-brain-barrier. A small amount crossed the placenta barrier in animal studies (≤0.3% of the dose were found in rabbit fetuses). Following intrathecal administration, maximum iodine concentrations of 4.5% of the administered dose per total plasma volume were observed after 3.8 hours.

Following administration in the biliary and/or pancreatic duct during endoscopic retrograde cholangiopancreaticography (ERCP), iodinated contrast agents are systemically absorbed and reach peak plasma concentrations between 1 and 4 h post administration. Maximum serum iodine levels following a mean dose of about 7.3g iodine were about factor 40 lower compared to maximum serum levels reached after

respective intravenous doses.

5.2.3 Metabolism

Iopromide is not metabolized.

5.2.4 Elimination

The terminal elimination half-life is approximately 2 hours, irrespective of the dose.

In the dose range tested, the mean total clearance of iopromide amounts to 106 ± 12ml/min and is similar to the renal clearance of 102 ± 15ml/min. Thus, excretion of iopromide is almost exclusively renal. Only about 2% of the dose administered is excreted via the fecal route within 3 days.

Approximately 60% of the dose are excreted within 3 hours after intravenous administration via urine. In the mean ≥93% of dose were recovered within 12 hours. Excretion is essentially complete within 24 hours.

Following administration into the biliary and/or the pancreatic duct for ERCP, total iodine serum concentrations returned to pre-dose levels within 7 days (between 4 to 21 days).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium disodium edetate
Hydrochloric acid (for pH adjustment)
Sodium hydroxide (for pH adjustment)
Tromethamine
Water for injection

6.2 Incompatibilities

Ultravist must not be mixed with any other medicinal products to avoid the risk of possible incompatibilities.

6.3 Shelf life

Please refer to labels.

6.4 Special precautions for storage

Protect from light and ionizing radiation. Do not store above 30°C.
Store all drugs properly and keep them out of reach of children.

6.5 Instructions for use/handling

Ultravist should be warmed to body temperature prior to use.

6.5.1 Visual Inspection

Ultravist is supplied ready to use as a clear, colorless to pale yellow solution and free of particles.

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. As Ultravist is a highly concentrated solution, crystallization (milky-cloudy appearance and/or sediment at bottom, or floating crystals) may occur very rarely.

6.5.2 Ampoules/vials

The contrast medium solution should not be drawn into the syringe or the infusion bottle attached to the infusion set until immediately before the examination.

The rubber stopper should never be pierced more than once to prevent large amounts of microparticles from the stopper getting into the solution. The use of cannulas with a long tip and a max. diameter 18 G is recommended for piercing the stopper and drawing up the contrast medium (dedicated withdrawal cannulas with a lateral aperture, e.g. Nocore-Admix cannulas, are particularly suitable).

Any contrast solution not used in one examination for a given patient is to be discarded.

6.5.3 Large volume containers (only for intravascular administration)

The following applies to the multiple withdrawal of contrast medium from containers of 200 ml or more:

The multiple withdrawal of contrast medium must be done utilizing a device approved for multiple use.

The rubber stoppers of the bottle should never be pierced more than once to prevent large amounts of microparticles from the stopper getting into the solution.

The contrast medium must be administered by means of an automatic injector or by other approved procedures which ensure sterility of the contrast medium.

The tube from the injector to the patient (patient’s tube) must be replaced after every patient to avoid cross contamination.

The connecting tubes and all disposable parts of the injector system must be discarded when the infusion bottle is empty or ten hours after first opening the container.

Instructions of the device manufacturer must be followed.

Unused Ultravist in opened containers must be discarded ten hours after first opening the container.

6.6 Presentation

Ultravist 300
Vials of 20 ml, Bottles of 50 ml, 100 ml, 150 ml, 200 ml, 500 ml

Ultravist 370
Vials of 30 ml, Bottles of 50 ml, 100 ml, 200 ml, 500 ml
Not all presentations may be available locally.

Manufacturer
Bayer AG
Müllerstraße 178
13353 Berlin
Germany

Date of last revision:
January 2023