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Experience gives
confidence.
Ultravist®
Iopromide

Ultravist® gives U confidence.

Ultravist® is a non-ionic, monomeric, low-osmolar, extracellular X-ray contrast medium (LOCM). It is highly effective, and can be used with all modern X-ray techniques including conventional radiography, angiography and computed tomography.

200+ million

Ultravist®-enhanced CT scan procedures worldwide.

That's as if the whole population of Paris were examined 89 times using Ultravist®.

15+ million

Ultravist®-enhanced procedures each year.

That almost equals the population of the Netherlands.

40,000

patients are examined using Ultravist® every day.

That's more than one patient every two seconds.

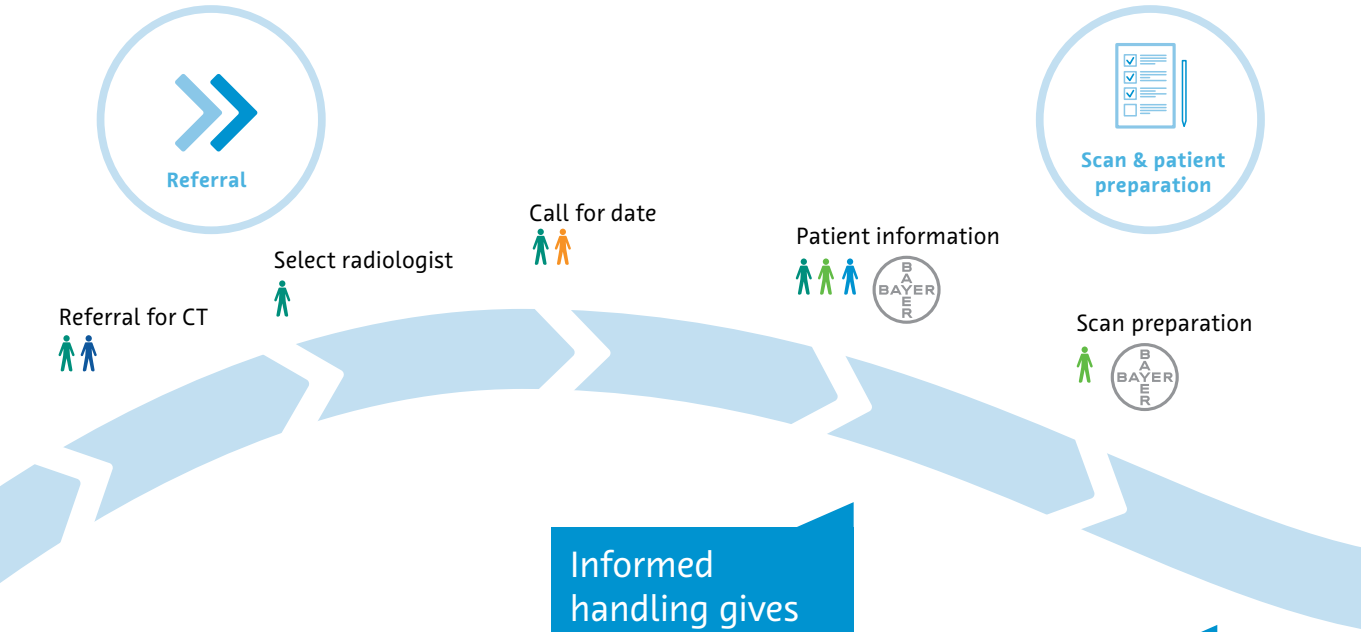
150,000

participants in Ultravist® studies.

That's more than the number of people passing through London Gatwick airport every day.

Full support gives U better care.

For optimal image quality and patient safety you need to look beyond just pure iodine. Bayer assists with every step of the patient journey.



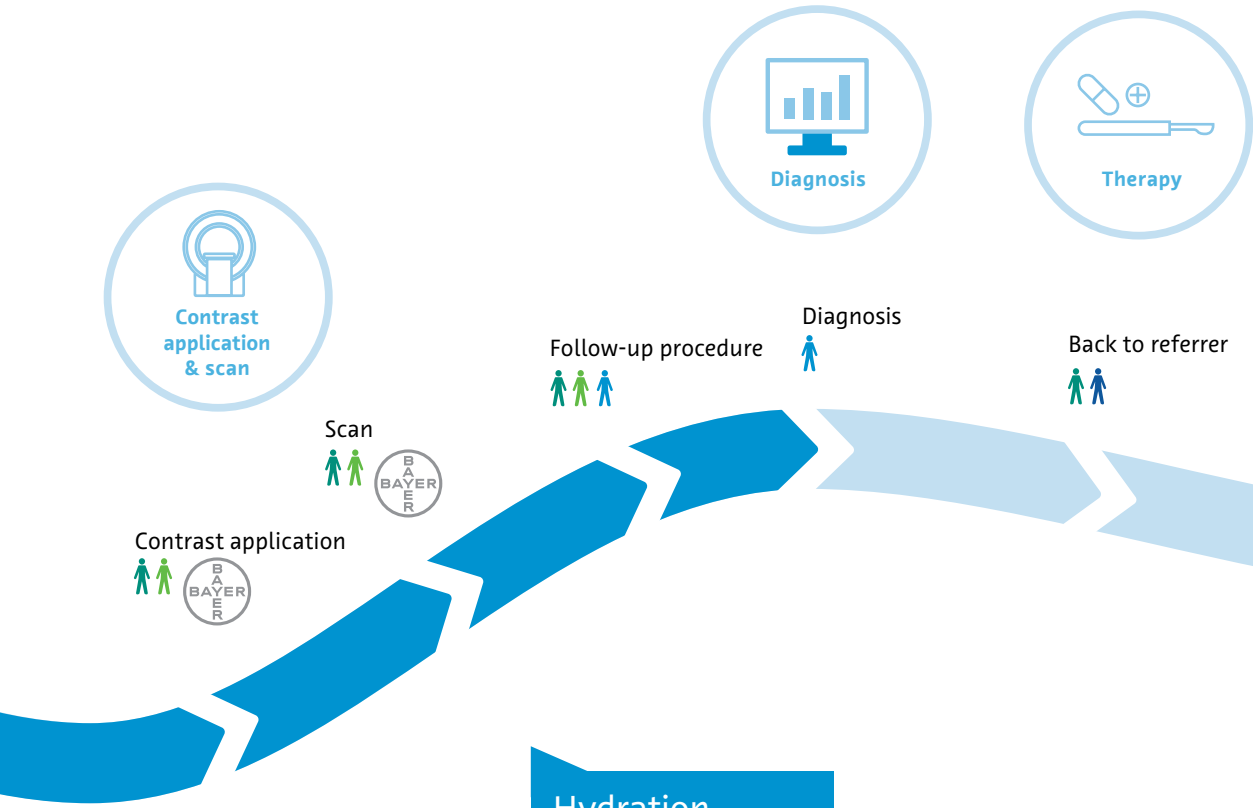
Informed handling gives U trust.

page 6–7

Good care gives U calmer patients.

page 8–9

Patient · Radiologist · Assistant · Referring Physician · Technician/Radiographer



Attention gives U better assurance.

page 10–11

Hydration gives U less risk of CIN.

page 12–13

Informed handling gives U trust.

Handle hygienically under sterile and aseptic conditions. If using non-disposable equipment, meticulous care should be taken to prevent contamination from cleansing agent residue.

Check contrast media before use. Discard in the event of container damage, discoloration or the presence of visible particles.

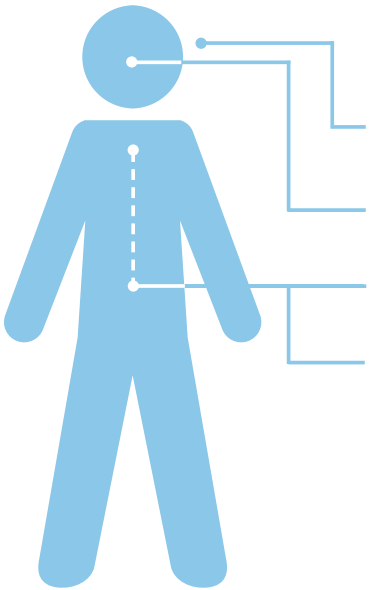
Warm contrast agent to body temperature. This will reduce viscosity, making it easier to administer and more comfortable for the patient.

Do not dilute contrast media with other drugs, solutions or nutritional mixtures.

Avoid extravasation by using plastic, large-bore cannulas. Plastic is unlikely to penetrate vessel walls accidentally.

Minimize risk of thrombosis by combining iodinated contrast media with soluble anticoagulant and careful cannula technique. Cleanse cannula with heparinized saline frequently and thoroughly.

Patient protection.



Which radiation protection method?

1	Cranial CT:	Thyroid shield[1]
2	Paranasal sinus CT:	Lens shield[2]
3	Chest CT:	Lead apron[3]
4	Abdominal CT:	Testicle capsule[1]

Good care gives U calmer patients.

Perceived side effects are often influenced by the patient's mindset.

- "Not all symptoms experienced by patients in the hour after contrast medium injection are adverse reactions to the contrast agent." [4]

- "The most important factors in the production of contrast media reactions are the patient's fear and apprehension." [5]

Minimizing patient anxiety.

Talking the patient through the process can help put them at ease and improve results. Clarify the examination procedure, the risks and what you need from them.

Explain:

Before

- ☑ that the radiation level is safe and no more than what the average person is exposed to over a year.
- ☑ that the scan takes only a few seconds and that most of the allotted time (30–60 minutes) is spent getting ready for it.

During

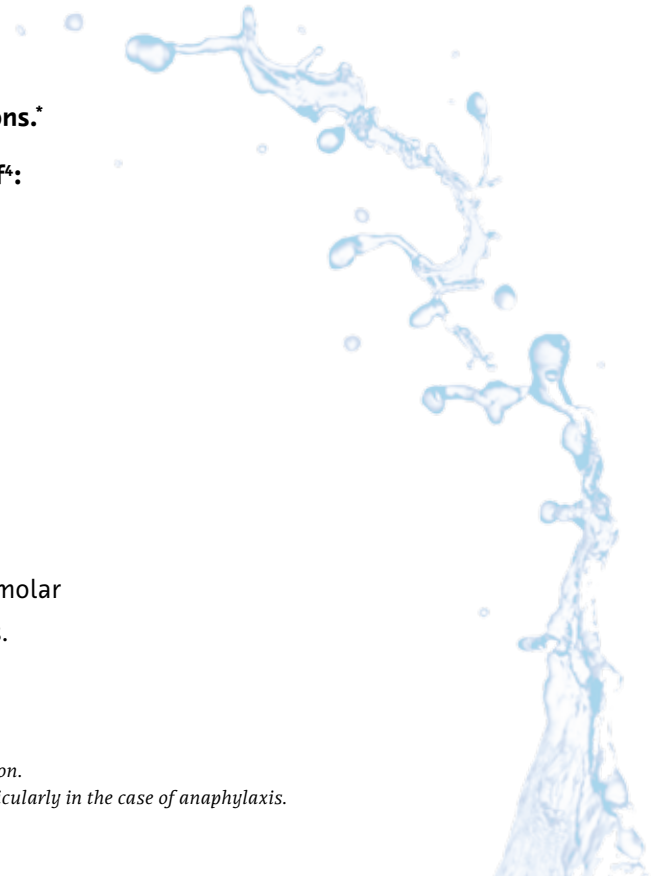
- ☑ what they need to do: empty pockets, remove jewelry, lie on CT scanner table, stay still and hold breath if asked to do so.
- ☑ what the purpose of the contrast medium is and how it will be administered.

After

- ☑ how the CT scan will create a 3D rendering of the target area from multiple X-rays.
- ☑ that they should drink plenty of fluids for 24 hours after the examination (unless a doctor has advised them not to).

Attention gives U assurance.

Awareness means staying alert to possible risk factors.



Identifying patients at risk of acute reactions.*

Pay attention to patients with a history of[4]:

- Moderate or severe acute reactions to any iodine-based contrast medium.
- Unstable asthma.
- Atopy requiring medical treatment.

Contrast medium-related risk factors[4]:

- High-osmolar ionic contrast media.
- There is no difference in the frequency of acute reactions between non-ionic low-osmolar and non-ionic iso-osmolar contrast agents.

**Adverse effects occurring within 60 minutes of administration.*
***There is limited data on the efficacy of premedication, particularly in the case of anaphylaxis.*

Reducing the risk of acute reactions.

- Use a non-ionic contrast medium for all patients.
- For patients with a history of adverse reactions, consider using a different iodine-based contrast medium.
- For other at-risk patients, consider premedication** (e.g. prednisolone) or alternative procedures that don't require iodine-based contrast media.

- **Prepare for acute reactions in all patients** by having resuscitation drugs and equipment at hand and keeping the patient observed for 30 minutes after contrast media administration.
- **Pre-warming iodine-based contrast media** is considered best practice. Warm contrast media has been shown to comfort patients and there is a small amount of data to suggest it reduces the frequency of adverse events.
- **For extravascular administration** take the same precautions as for intravascular to avoid transference into the circulatory system.

Hydration gives U less risk of CIN.

When it comes to delayed contrast reactions, Contrast-Induced Nephropathy is the most common concern. For patients at risk, hydration is key.

"The major preventive action to mitigate the risk of CIN is to provide intravenous volume expansion prior to contrast medium administration."[6]

IV hydration (saline)[4]

Recommended if slow hydration is possible

Pros

- Controllable and reliable
- Lasts for several hours

Cons

- Needs to start at least 6 hours before and after examination

Oral hydration (water)[7]

Recommended for rapid hydration

Pros

- Easy to use
- Cost-effective
- Desired effect within 20–30 mins.

Cons

- Short duration of protective effect

Risk factors for CIN.

Patient risk factors (left column) need to be countered by reducing procedural risk factors (right column)[4].

Patient-related risk factors

GFR <45 ml / min / 1.73 m²
before intravenous administration

GFR <60 ml / min / 1.73 m²
before intra-arterial administration

Especially in combination with:

- Diabetic Nephropathy
- Dehydration
- Cardiac insufficiency (NYHA Class 3-4) and low LVEF
- Fresh myocardial infarction (<24 h)
- Intra-aortal balloon pump
- Peri-procedural hypotonia
- Low hematocrit
- Age over 70
- Simultaneous application of nephrotoxic drugs
- Renal insufficiency or acute Renal failure

Thinking about the procedure

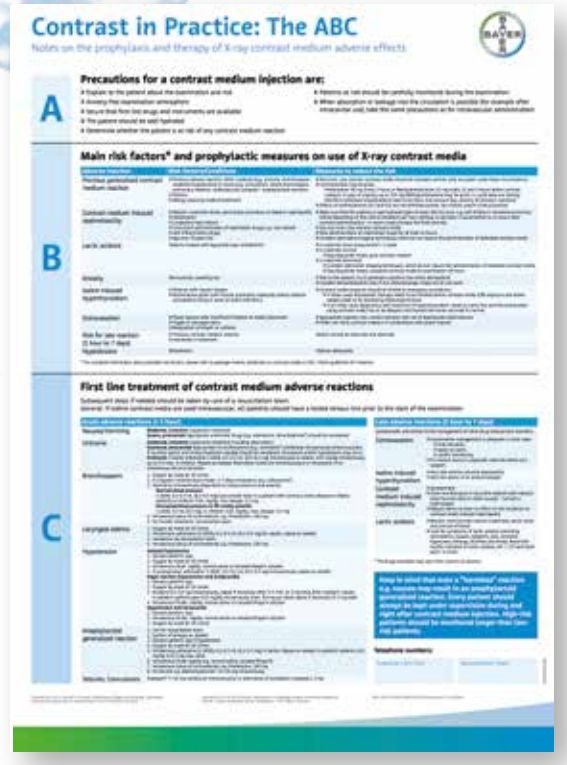
- Intra-arterial administration of contrast medium
- High-osmolality agents (ionic iodinated contrast agents)
- Large doses of contrast medium
- Multiple contrast medium administrations within a few days

Preparation gives U rapid response.

Severe reactions to low osmolar contrast media occur rarely, regardless of what particular LOCM you use. Despite this, you and your team must be prepared to treat any adverse reactions.

Such adverse effects can be life threatening so prompt handling is crucial. It is advisable to have resuscitation drugs on hand in the examination room.

Most severe reactions occur within 30 minutes of injection. Patients should remain in the medical environment during this timeframe.


Contrast in Practice: The ABC

Notes on the prophylaxis and therapy of X-ray contrast medium adverse effects

A

Precautions for a contrast medium injection are:

B

Main risk factors* and prophylactic measures on use of X-ray contrast media

C

First line treatment of contrast medium adverse reactions

› **The ABC poster is available from Bayer.**

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Choose Ultravist® for a clear direction from diagnosis to care.

We are committed to building strong partnerships with radiologists. By providing high-quality products, education programs and extensive support, we enable medical professionals to focus on what they do best.

If we can assist you with more information on Ultravist® or any other Bayer product or service, please contact us at **radiology.bayer.com**

1 Hidajat et al. (RöFo, November 1996)
The efficacy of lead shielding in patient dosage reduction in computed tomography.
2 Hein et al. (European Radiology, July 2002)
Low-dose CT of the paranasal sinuses with eye lens protection: effect on image quality and radiation dose.
3 Iball et al. (British Journal of Radiology, November 2011)
Organ and effective dose reduction in adult chest CT using abdominal lead shielding.
4 ESUR Guideline 9.0 http://www.esur-cm.org
5 Lalli AF. (Radiology, January 1980)
Contrast media reactions: data analysis and hypothesis.
6 ACR Manual on Contrast Media – Version 10.2, 2016
7 Schmidt et al. (Physiologie des Menschen – 31st Edition Springer, 2013)
Chapter 30: P. Persson, Wasser- und Elektrolythaushalt.

ULTRAVIST® 150/240/300/370 Composition: Ultravist® 150, 240, 300, 370: 1 ml contains 0.312 g, 0.499 g, 0.623 g, 0.769 g iopromide in aqueous solution. For diagnostic use! Indications: Ultravist® 240/300/370: For intravascular use and use in body cavities. Contrast enhancement in computerised tomography (CT), arteriography and venography, intravenous/intraarterial digital subtraction angiography (DSA); intravenous urography, use for ERCP, arthrography and examination of other body cavities. Ultravist® 150: For intraarterial digital subtraction angiography (DSA), checking the patency of a dialysis shunt. Ultravist® 240: Also for intrathecal use. Ultravist® 370: Especially for angiocardiography. Ultravist® 150/300/370: Not for intrathecal use. 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, beta blockers, latent hyperthyroidism or goiter, severe cardiac or cardiovascular diseases; very poor general state of health, pulmonary edema, severe renal insufficiency, severe liver dysfunction in case of severe renal insufficiency, metformin therapy, symptomatic cerebrovascular diseases, cerebral convulsive disease, myeloma or paraproteinaemia, pheochromocytoma, autoimmune disorders, myastenia gravis, alcoholism, homocystinuria, pregnancy and neonates, especially preterm infants. Undesirable effects (please refer to the contraindications and warnings and precautions sections): Most frequently observed adverse drug reactions (4 %) are: Headache, nausea and vasodilatation; most serious adverse drug reactions 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. Common: Dizziness, headache, dysgeusia, blurred/disturbed vision, chest pain/discomfort, hypertension, vasodilatation, vomiting, nausea, pain, injection site reactions (various kinds, e.g. pain, warmth, edema, inflammation and soft tissue injury in case of extravasation), feeling hot. Uncommon: Hypersensitivity/anaphylactoid reactions (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), vasovagal reactions, confusional state, restlessness, paraesthesia/hypoaesthesia, somnolence, arrhythmia, hypotension, dyspnea, abdominal pain, edema. Rare: Anxiety, cardiac arrest, myocardial ischemia, palpitations. Frequency not known: Thyrotoxic crisis, thyroid disorder, coma, cerebral ischaemia/ infarction, stroke, brain edema, convulsion, transient cortical blindness, loss of consciousness, agitation, amnesia, tremor, speech disorders, paresis/paralysis, hearing disorders, myocardial infarction, cardiac failure, bradycardia, tachycardia, cyanosis, shock, thromboembolic events, vasospasm, pulmonary edema, respiratory insufficiency, aspiration, dysphagia, salivary gland enlargement, diarrhoea, bullous conditions (e.g. Stevens-Johnson's or Lyell syndrome), rash, erythema, hyperhydrosis, compartment syndrome in case of extravasation, renal impairment, acute renal failure, malaise, chills, pallor, body temperature fluctuation. Based on experience with other nonionic contrast media, the following undesirable effects may occur with intrathecal use in addition to the undesirable effects listed above: Nervous, psychiatric: Neuralgia, meningism (common), paraplegia psychosis, aseptic meningitis, EEG-changes (rare). General disorders and administration site conditions: Micturition difficulties (uncommon), back pain, pain in extremities, injection site pain (rare). Headache, including severe prolonged cases, nausea and vomiting occur commonly. The majority of the reactions after myelography or use in body cavities occur some hours after the administration. ERCP: In addition to the undesirable effects listed above, the following undesirable effects may occur with use for ERCP: Elevation of pancreatic enzyme levels (common), pancreatitis (rare). Use in other body cavities: The possibility of pregnancy must be excluded before performing hysterosalpingography. Inflammation of the bile ducts or salpinx may increase the risk of reactions following ERCP or hysterosalpingography procedures. Low osmolar water-soluble contrast media should be routinely used in gastrointestinal studies in newborns, infants and children because these patients are at particular risk for aspiration, intestinal occlusion or extraluminal leakage into the peritoneal cavity. Instructions for use/handling: Ultravist® should be warmed to body temperature prior to use. Contrast media should be visually inspected prior to use and must not be used, if discoloured, nor in the presence of particulate matter (including crystals) or defective containers. Date of revision of the text: March 2014. Please note! For current prescribing information refer to the package insert and/or contact your local Bayer HealthCare organisation. Bayer Pharma AG, 13342 Berlin, Germany. Adverse reactions can be reported to GPV.CaseProcessing@bayer.com

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