PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ULTRAVIST 300 20 mL, 50 mL, 75 mL, 100 mL, 125 mL, 200 mL, 500 mL
ULTRAVIST 370 50 mL, 100 mL, 125 mL, 200 mL, 500 mL
Solution for injection/infusion
Iopromide
Sugar free

Read all of this leaflet carefully before you are given ULTRAVIST
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ULTRAVIST has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. WHAT ULTRAVIST is and what it is used for
2. What you need to know before you are given ULTRAVIST
3. How to use ULTRAVIST
4. Possible side effects
5. How to store ULTRAVIST
6. Contents of the pack and other information

1. What ULTRAVIST is and what it is used for

ULTRAVIST is an injectable contrast medium (a dye) which contains iodine. It is used to clearly show in X-rays the area of your body that your doctor wants to investigate. X-rays, like radio waves, can pass through objects and can be focused to make a picture. When you have an X-ray, the beam of rays goes through your body where it is absorbed to differing degrees by different tissues such as bones, muscles and organs. When the rays come out on the other side, they make a pattern of light and shade on a film. ULTRAVIST helps to make this pattern clearer. The film is then examined by a specialist who will make a diagnosis.

This medicine is for diagnostic use only

2. What you need to know before you use ULTRAVIST

ULTRAVIST should not be administered to you
- If you have an overactive thyroid gland (uncontrolled hyperthyroidism).
- If you are allergic to iodine.
- if you are pregnant or if you have acute inflammation in your pelvic cavity, X-ray examination of a woman's uterus and fallopian tubes that uses a special form of x-ray called fluoroscopy and a contrast material (Hysterosalpingography) must not be performed.

- If you are pregnant, Safety of ULTRAVIST in pregnancy has not been established. Do not use ULTRAVIST during pregnancy.
- Do not have an examination of the pancreas (ERCP) performed if there is inflammation of the pancreas (acute pancreatitis).
- **ULTRAVIST 300 and 370 are not indicated for injection into the space around the spinal cord (intrathecal use).**

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection

Before you are given ULTRAVIST, it will be warmed to body temperature, since it is better tolerated and can be injected more easily because of reduced viscosity.

Before you are given ULTRAVIST your healthcare professional will visually inspect the contrast medium and will not use it, if it is discoloured, 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.

Your healthcare professional will not mix ULTRAVIST with any other medicines to avoid the risk of possible incompatibilities.

Before you are given ULTRAVIST, tell your doctor if you are anxious - pronounced states of excitement, anxiety and pain may increase the risk of side effects or intensify contrast medium-related reactions (see section 'Possible side effects').

ULTRAVIST should not be given to you, if you are dehydrated (have not taken enough fluids).
To avoid this, your doctor will ensure that you will have taken enough fluids before your examination (see section 'Take special care with ULTRAVIST').
This is especially important if you have multiple myeloma (cancer of the plasma cells in bone marrow), diabetes mellitus, polyuria (passing large volumes of urine) or oliguria (reduced urine production), hyperuricemia/gout (high level of uric acid in the blood), you are using medicines called diuretics or water pills, if you are elderly, a newborn, infant or small child.

Tell your doctor if you have kidney problems. Your doctor will ensure that you are well hydrated before your examination. However, giving IV fluids (fluid into your veins) if you have kidney problems is not recommended.
Tell your doctor if you have severe kidney problems accompanied with heart disease. Giving IV fluids (fluid into your veins) can be dangerous for your heart.

Since testing for a potential allergy to the contrast medium using a small test dose of ULTRAVIST prior to your examination has no predictive value and may even lead to serious and even fatal hypersensitivity reactions, your doctor will not perform pretesting.

Take special care with ULTRAVIST

Fatal reactions have been associated with the administration of ULTRAVIST. Precaution measures are in place, you will be observed for a possible severe reaction during and for at least 30 to 60 minutes after administration. Although delayed reactions may occur (after hours to days).

- Hypersensitivity/allergy-like reactions

Tell your doctor if you are hypersensitive (allergic) to ULTRAVIST or any excipient of ULTRAVIST, if you ever had a previous hypersensitivity reaction to any other contrast medium, if you have or ever had bronchial asthma or other allergies as you may have a higher risk of having an allergy-like reaction (including severe reactions) to ULTRAVIST. Your doctor will decide whether the intended examination is possible or not.

These allergy-like reactions are characterized by cardiovascular (heart and blood vessels), respiratory (lung) and cutaneous manifestations (skin reactions such as mild swelling of the face, lips, tongue or throat, conjunctivitis, coughing, itching, running nose, sneezing and hives).

Allergy-like reactions ranging from mild to severe reactions including shock are possible (see section 'Possible side effects'). Such reactions are irregular and unpredictable in nature. Most of them occur within 30 minutes of administration. However, delayed reactions (after hours to days) may occur.

Tell your doctor if you are taking beta-blockers, a medicine used to treat high blood pressure since beta agonists (medicines used to treat adverse reactions of ULTRAVIST) may not be effective.

Tell your doctor if you suffer from cardiovascular disease (disease of the heart and blood vessels) since you might be more susceptible to serious or even fatal outcomes when having a severe hypersensitivity reaction.

Your doctor will observe you after you receive ULTRAVIST and will be prepared to institute emergency measures in case of severe hypersensitivity (allergic) reactions.
Your doctor might give you a corticosteroid prior to your examination, a medicine like cortisone (e.g. used to treat inflammation), when you have an increased risk of acute allergy-like reactions (e.g. if you had a previous moderate or severe acute reaction, if you have asthma or an allergy requiring medical treatment).

- Thyroid dysfunction
  Tell your doctor if you have hyperthyroidism (overactive thyroid) or goitre (enlarged thyroid gland) as iodinated contrast media may in this situation induce hyperthyroidism and thyrotoxic crisis (severe complication of an overactive thyroid). The doctor will decide whether the intended examination is possible or not. Your thyroid function may be tested before receiving ULTRAVIST and you may be given thyrostatic medication.
  The doctor will test the thyroid function of new-borns who have been exposed to ULTRAVIST either during pregnancy or after birth, because too much iodine can cause hypothyroidism (underactive thyroid gland), which might require treatment.

- Central nervous system disorders
  Tell your doctor if you have a circulatory problem in the brain, e.g. a history of stroke and other conditions involving blood brain barrier damage, cerebral oedema (fluid build-up around the brain) or acute demyelination (damage of the protecting covering-myelin sheath surrounding nerve fibres surrounding brain, optic nerve and spinal cord).

  Tell your doctor if you have CNS (central nervous system) disorders, e.g. a history of seizures/fits. In this case or in case of a lowered seizure threshold or an increased permeability of your blood-brain barrier (e.g. due to special medication) you may be at an increased risk to experience neurological complications.
  Neurological complications are more frequent in cerebral angiography and related procedures (X-ray examination of the vessels in the brain).

- Acute Kidney Injury
  If you receive ULTRAVIST for intravascular injection (fluid into your blood vessels) there is a risk that you may develop a kidney injury after the injection (Post Contrast-Acute Kidney Injury / PC-AKI). As a result, your kidneys may not work properly for a short time. Some patients experience kidney failure.
  This is especially the case if you have any of the following conditions:
  - a pre-existing renal insufficiency (kidneys do not work properly). For more information see also section '3. How you will be given ULTRAVIST'/'Patients with renal (kidney) impairment',
  - diabetes mellitus,
  - multiple myeloma (cancer of the plasma cells in bone marrow),
  - paraproteinaemia (excessive amounts of a paraprotein in the blood),
  - if you suffer from dehydration or
  - if you are receiving large or repeated doses of ULTRAVIST,

  If you are on dialysis and do not have any residual kidney function, you may receive ULTRAVIST, since it is cleared by the dialysis process.

- Cardiovascular disease (disease of the heart and blood vessels)
  If you receive ULTRAVIST for intravascular injection (fluid into blood vessels) and suffer from a significant cardiac (heart) disease or from severe coronary artery disease (decreased blood flow to the heart muscle, chest pain), you may be at an increased risk of developing haemodynamic changes (blood circulation changes) and arrhythmia (disturbance in the rate or rhythm of the heartbeat). If you suffer from heart failure, the injection of ULTRAVIST may lead to pulmonary oedema (fluid accumulation in the lungs). (see section 'Before you are given ULTRAVIST'\ 'Patients with renal (kidney) impairment')

- Pheochromocytoma
  If you receive ULTRAVIST for intravascular injection (fluid into your blood vessels) and suffer from pheochromocytoma (disease of adrenal glands), you may be at an increased risk of getting a hypertensive crisis (severe form of high blood pressure).

- Myasthenia gravis
  If you receive ULTRAVIST for intravascular injection (fluid into blood vessels) and suffer from myasthenia gravis (chronic disorder of the muscles), your symptoms of myasthenia gravis may get worse.

Other medicines with ULTRAVIST

Always tell your healthcare provider if you are taking any other medicine. This includes complementary or traditional medicines, but particularly any of the following:

- Biguanides(metformin), a medicine used to treat diabetes mellitus. If you suffer from acute kidney failure or severe chronic kidney disease, biguanides may accumulate in your body which leads to lactic acidosis (too much acid in the blood). Since the administration of ULTRAVIST may lead to kidney problems or an aggravation of kidney problems, you may be at an increased risk of getting lactic acidosis.
- Beta-blockers, medicines used to treat high blood pressure or other heart conditions. If you suffer from asthma or experience hypersensitivity reactions while taking a beta-blocker, you may not respond to treatment effect of beta agonists (treatment that can be used to treat side effects caused by an allergic reaction to ULTRAVIST).

- Interleukin-2, a medicine to treat cancer since you may suffer from delayed side effects of ULTRAVIST.
- Radioisotopes for diagnosis and treatment of thyroid disorders (altered thyroid gland function). The diagnosis and treatment of thyroid disorders may be impeded for up to several weeks after administration of ULTRAVIST due to reduced radioisotope uptake.

Your doctor will advise you how to take these medicines before the examination.

ULTRAVIST with food and drink
Adequate fluid intake should be maintained when receiving ULTRAVIST.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before you are given ULTRAVIST.
Clinical studies in pregnant women have not been conducted.

Safety of ULTRAVIST in breastfeeding has not been investigated.

Driving and using machines

It is not known if ULTRAVIST affects the ability to drive or use machines.

ULTRAVIST contains sodium

ULTRAVIST contains less than 1 mmol (23 mg) sodium per dose (based on the average amount given to a 70 kg person), i.e. essentially 'sodium-free'.

3. How to use ULTRAVIST

Do not share medicines prescribed for you with any other person.
ULTRAVIST will be given to you by a trained healthcare professional.

ULTRAVIST is injected by a doctor via a small needle into a blood vessel, usually in the back of your hand or inside the forearm. ULTRAVIST can also be given into other body cavities. It will be administered immediately before your X-ray examination.

Dosage for intravascular injection (fluid into blood vessels)

The actual dose of ULTRAVIST that is right for you will be worked out by the doctor and will depend on your age, body weight, the area to be investigated and which examination technique will be performed. The speed at which ULTRAVIST is injected, and the length of time until the examination is performed will also depend on the type of the technique done. For most types of X-ray, only a single dose of ULTRAVIST will be required.

Because of possible severe reactions, you will be observed in case there might be any initial side effects after the administration of ULTRAVIST.

The doctor will take care regarding the dose, the technical performance of the radiological procedure and the general condition when giving ULTRAVIST to young infants (< 1 year) and especially

newborns as they are susceptible to electrolyte imbalance and haemodynamic alterations (blood circulation changes).

No specific dose adjustment is required for elderly patients.

No dosage adjustment is considered necessary in patients with liver impairment, since only a small amount of iopromide is eliminated via faeces.
Since iopromide, the active substance of ULTRAVIST, is excreted almost exclusively in an unchanged form via the kidneys, the elimination of iopromide is prolonged if you suffer from kidney impairment. The minimum possible dose will be given to reduce the risk of additional contrast media-induced kidney injury impairment (see section 'What you need to know before you are given ULTRAVIST/Take special care with ULTRAVIST').

If you use more ULTRAVIST than you should

Since a healthcare professional will administer this medicine, he/she will control the dosage. However, in the event of overdosage your doctor will manage the symptoms.

Symptoms of intravascular overdose may include fluid and electrolyte imbalance, kidney failure, cardiovascular (heart and blood vessels) and pulmonary (lung) complications. Your fluids, electrolytes and kidney function may be monitored. Your doctor may also decide to eliminate ULTRAVIST from your body by dialysis.

4. Possible side effects

ULTRAVIST can have side effects. Not all side effects reported for ULTRAVIST are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving ULTRAVIST, please consult your doctor, pharmacist or other healthcare professional for advice.

Severe and life-threatening reactions as well as deaths have been reported.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Anaphylactoid (allergy-like) shock, respiratory arrest (breathing arrest), bronchospasm (breathing difficulties), laryngeal oedema (swelling of the voice box), pharyngeal oedema (throat swelling), asthma, coma, cerebral infarction (decreased blood flow to parts of the brain), stroke, brain oedema (fluid accumulation in the brain), convulsion (seizure/fit), dysrhythmia (disturbances in the rate or rhythm of the heartbeat), cardiac arrest (heart stops), myocardial ischaemia (painful heart condition caused by the lack of blood flow to the heart), myocardial infarction (heart attack), cardiac failure (heart failure), bradycardia (slow heartbeat), cyanosis (bluish colouration of the skin and mucous membrane due to lack of oxygen), hypotension (low blood pressure), shock, dyspnoea (shortness of breath), pulmonary oedema (fluid accumulation in the lungs), respiratory insufficiency (lungs cannot take in sufficient oxygen or expel sufficient carbon dioxide) and aspiration (taking foreign material into the lungs).

These are all very serious side effects. If you have them, you may have had a serious reaction to ULTRAVIST. You may need urgent medical attention or hospitalisation.

Most frequent side effects

Dizziness, headache, taste disturbances, blurred/disturbed vision, chest pain/discomfort, high blood pressure, warm feeling (vasodilatation), nausea, vomiting heat or pain sensations, pain, if the contrast medium is not injected exactly into the blood vessel: local pain, mild warmth and swelling, inflammation and tissue injury.

Frequent side effects

Allergy-like reaction, shortness of breath, disturbance in respiratory rate, swelling of the mucous membranes, asthma, hoarseness, swelling of the face, tongue or throat, difficulty in breathing (bronchospasm, laryngeal/pharyngeal spasm), build-up of fluid in the lungs, breathing arrest, throat irritation, conjunctivitis, secretion of tears, sneezing, coughing, difficulty in swallowing, swelling of salivary glands, swelling of the tongue, face, lips or throat, severe skin disease (pain, reddening, large blisters, peeling of layers of skin, bleeding in the lips, eyes etc.), restlessness, blurred/disturbed vision, changes in heart rate, abnormally low blood pressure, shortness of breath (dyspnoea), warm feeling (vasodilatation), state of confusion, tingling or numbness of the hands or feet/decreased sensitivity, somnolence, stomach pain, swelling from excessive fluid accumulation, sneezing, coughing, vomiting, taste disturbance, hives, itching, rash, redness of the skin, kidney disease (only after injection into a blood vessel), generally feeling unwell, chills, sweating, fainting.

Less frequent side effects

Allergy-like reaction with dangerous decrease in blood pressure (shock) (including fatal cases), overactive thyroid gland (hyperthyroidism, thyrotoxic crisis), underactive thyroid gland (hypothyroidism), tingling or numbness of the hands or feet/decreased sensitivity, confusion, anxiety, agitation, loss of memory, speech disorders, somnolence, unconsciousness, coma, tremors, seizures, weakness causing loss of movement/paralysis, decreased blood flow to parts of the brain, stroke, temporary blindness, conjunctivitis, secretion of tears, hearing disorders, fast or irregular heartbeats (palpitations), chest pain/tightness, slow heartbeat, fast heartbeat, heart attack, disease of the heart, blue lips, low blood pressure, high blood pressure, dangerous decrease in blood pressure (shock), spasm in blood vessels (only after injection into a blood vessel) blocking of a blood vessel by a blood clot (only after injection into a blood vessel), runny nose, shortness of breath, disturbance in respiratory rate, swelling of the mucous membranes, asthma, hoarseness, swelling of the face, tongue or throat, difficulty in breathing (bronchospasm, laryngeal/pharyngeal spasm), build-up of fluid in the lungs, breathing arrest, throat irritation, difficulty in swallowing, swelling of salivary glands, stomach pain, diarrhoea, swelling of the tongue, face, lips or throat, severe skin disease (pain, reddening, large blisters, peeling of layers of skin, bleeding in the lips, eyes etc.), severe kidney disease, pale skin, changes in body temperature, swelling of the skin, if the contrast medium is not injected exactly into the blood vessel: local pain, mild warmth and swelling, inflammation and tissue injury.

Examination of the pancreas (ERCP)

In addition to the undesirable effects listed above, the following side effects may occur with use for ERCP: elevation of pancreatic enzyme levels (common), inflammation of the pancreas (rare).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. Alternatively, you can report to Bayer SafeTrack site (https://www.safetrack-public.bayer.com). By reporting side effects, you can help provide more information on the safety of ULTRAVIST.

5. How to store ULTRAVIST

For single dose use. Discard unused portion.

Store ULTRAVIST out of reach of children.

Until required for use, ULTRAVIST must be stored in the original outer carton at or below 30 °C. Protect from light, heat and secondary X-rays.
Do not use after the expiry date stated on the carton and the container label.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ULTRAVIST contains

The active substance is iopromide
1 mL ULTRAVIST 300 contains 623 mg iopromide (equivalent to 300 mg iodine).
1 mL ULTRAVIST 370 contains 769 mg iopromide (equivalent to 370 mg iodine).
The other ingredients are calcium sodium edetate, hydrochloric acid (for pH adjustment), trometamol and water for injection.
Each mL contains 0.000534 mmol (equivalent to 0.0123 mg) of sodium (see section 'Before you are given ULTRAVIST/Important information about some of the ingredients of ULTRAVIST')

What ULTRAVIST looks like and contents of the pack

ULTRAVIST is a clear, very slightly brown, very slightly brownish-yellow or very slightly yellow, sterile, pyrogen-free solution.
ULTRAVIST is packed in the following packaging materials and sizes:

ULTRAVIST 300:	Colourless vials of 20 mL with grey plastic stoppers packed in a carton containing 10 vials.
ULTRAVIST 300:	Colourless bottles of 50, 75 or 100 mL with grey plastic stoppers packed in a carton containing 10 bottles.
ULTRAVIST 300:	Colourless bottles of 125 mL with grey plastic stoppers packed in a carton containing 5 or 10 bottles.
ULTRAVIST 300:	Colourless pre-filled plastic cartridges of 75, 100 and 125 mL packed into a carton containing 1x5 cartridges or 2x5 cartridges.
ULTRAVIST 300:	Colourless bottles of 200 mL with grey plastic stoppers packed in a carton containing 1 or 10 bottles.
ULTRAVIST 300:	Colourless bottles of 500 mL with grey plastic stoppers packed in a carton containing 1 or 8 bottles.
ULTRAVIST 370:	Colourless bottles of 50 or 100 mL with grey plastic stoppers packed in a carton containing 10 bottles.
ULTRAVIST 370:	Colourless bottles of 125 mL with grey plastic stoppers packed in a carton containing 5 or 10 bottles.

ULTRAVIST 370:	Colourless pre-filled plastic cartridges of 100 and 125 mL packed into a carton containing 1 x 5 cartridges or 2 x 5 cartridges.
ULTRAVIST 370:	Colourless bottles of 200 mL with grey plastic stoppers packed in a carton containing 1 or 10 bottles.
ULTRAVIST 370:	Colourless bottles of 500 mL with grey plastic stoppers packed in a carton containing 1 or 10 bottles.

Holder of Certificate of Registration

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Registration numbers

ULTRAVIST 300 20 mL vial:	V/28/175
ULTRAVIST 300 50 mL bottle:	V/28/176
ULTRAVIST 300 75 mL bottle and pre-filled plastic cartridge:	28/28/0642
ULTRAVIST 300 100 mL bottle and pre-filled plastic cartridge:	V/28/177
ULTRAVIST 300 125 mL bottle and pre-filled plastic cartridge:	46/28/0109
ULTRAVIST 300 200 mL bottle:	33/28/0082
ULTRAVIST 300 500 mL bottle:	33/28/0083
ULTRAVIST 370 50 mL bottle:	V/28/178
ULTRAVIST 370 100 mL bottle and pre-filled plastic cartridge:	V/28/179
ULTRAVIST 370 125 mL bottle and pre-filled plastic cartridge:	46/28/0110
ULTRAVIST 370 200 mL bottle:	28/28/0643
ULTRAVIST 370 500 mL bottle:	33/28/0084