SELECT THE REQUIRED INFORMATION

PROFESSIONAL INFORMATION

PATIENT INFORMATION LEAFLET

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SCHEDULING STATUS: S4

PROPRIETARY NAMES AND DOSAGE FORM:

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

Please read 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 or your pharmacist.
- 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 ULTRAVIST CONTAINS:

ULTRAVIST contains the contrast-giving substance iopromide as active ingredient. The inactive ingredients are: calcium sodium edetate, hydrochloric acid, trometamol and water for injection.

ULTRAVIST 300
1 ml contains 623 mg iopromide (equivalent to 300 mg iodine).
ULTRAVIST 370
1 ml contains 769 mg iopromide (equivalent to 370 mg iodine).

WHAT ULTRAVIST IS AND WHAT IT IS USED FOR:

ULTRAVIST is an iodine-containing contrast medium for X-ray examinations.
Depending on the mode of administration and the administered strength ULTRAVIST provides visualisation of the veins and arteries, detection of abnormalities in the urinary system, kidney, brain, spine, heart and body cavities.

BEFORE YOU ARE GIVEN ULTRAVIST:

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.

Do not receive ULTRAVIST:

- If you have an overactive thyroid gland (hyperthyroidism).
- If you are allergic to iodine.
- If you have moderate to severe disturbances of kidney function.
- 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 or if you have acute inflammation in your pelvic cavity.
- Safety of ULTRAVIST in pregnancy has not been established. ULTRAVIST should not be used during pregnancy.
- Examination of the pancreas (ERCP) should not be 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).**

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).

- Allergy-like reactions have been observed after use of X-ray contrast media such as ULTRAVIST (see "Possible Side effects").
- Mild swelling of the face, lips, tongue or throat, conjunctivitis, coughing, itching, running nose, sneezing and hives which can occur irrespective of the amount administered, may be the first signs of incipient state of a severe reaction. Administration of the contrast medium must be discontinued immediately and if necessary - specific drug therapy must be administered into a vein.
- Delayed reactions may occur (see “Possible Side effects”).
- Examination of the pancreas and bile ducts may increase the risk of reactions in the presence of inflammation.

If you suffer from **any of the conditions listed below**, your doctor will decide whether the intended examination with ULTRAVIST is possible or not. **Tell your doctor if:**

- You are breastfeeding or intend to breastfeed. You should discuss with your doctor when to discontinue and resume breastfeeding;
- You suffer from allergy (e.g. seafood allergy, hay fever, hives) or bronchial asthma;
- You are allergic to iodine-containing contrast media, iopromide or any other ingredient of ULTRAVIST;
- You had a previous reaction to contrast media;
- You have disturbances of kidney function;
- You have heart and circulatory disease;
- You have disturbances in the rate or rhythm of the heartbeat;
- You have diabetes;
- You suffer from brain conditions with seizures or from other diseases of the nervous system;
- You have a circulatory problem in the brain, e.g. a history of stroke;
- You have a swelling of the neck caused by enlargement of the thyroid gland (goitre);
- You suffer from cancer of the blood cells (multiple myeloma), or an overproduction of special proteins (paraproteinemia), a condition of allergy against parts of your body, or a condition in which the muscles become weak and tire easily (myasthenia gravis);
- You have a special kind of high blood pressure caused by a rare tumour of the adrenal gland which sits near the kidney (phaeochromocytoma);
- You take special medicines daily or drink alcohol regularly.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before you are given ULTRAVIST.

You should not receive ULTRAVIST when you are pregnant or breastfeeding your infant.

Using other medicines with ULTRAVIST:

Always tell your healthcare professional if you are taking any other medicine. This includes complementary or traditional medicines.

Tell your doctor if you are taking or have taken any other medicines.

Some medicines may affect the way ULTRAVIST works in your body. These include:

- Beta-blockers, medicines used to treat high blood pressure or other heart conditions;
- Biguanides, one type of medicine used to treat diabetes;
- Neuroleptics, antidepressants;

- Interleukin;
- Radioactive substances for the thyroid gland.

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

HOW TO USE ULTRAVIST:

Do not share medicines prescribed for you with others:

You will be asked not to eat anything for 2 hours before the examination, but you may drink as usual. Further directions on this will be given by your doctor.

ULTRAVIST is injected by a doctor via a small needle into a 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.

The actual dose of ULTRAVIST that is right for you will be worked out by the doctor and will depend on your age, weight and the type of X-ray that is being done. The speed at which ULTRAVIST is injected, and the length of time until the X-rays are taken will also depend on the type of X-ray being 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.

If you receive 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.

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 serious side effects. You may need urgent medical attention.

Most frequent side effects include:

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 include:

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 include:

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).

STORING AND DISPOSING OF 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).

Vials and bottles:
Store in the outer cartons at room temperature (at or below 30 °C).
Prefilled plastic cartridges:
Store in the outer cartons at or below 30 °C.

PRESENTATION OF ULTRAVIST:

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.

IDENTIFICATION OF ULTRAVIST:

Clear, very slightly brown, very slightly brownish-yellow or very slightly yellow, sterile, pyrogen-free solution.
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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

NAME AND ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Bayer (Pty) Ltd
Reg. No.: 1968/011192/07
27 Wrench Road
ISANDO
1609

DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

Botswana:
Ultravist 300 20 ml: (S2) BOT1703106
Ultravist 300 50 ml: (S2) BOT1703107
Ultravist 300 75 ml: (S2) BOT1703108
Ultravist 300 100 ml: (S2) BOT1703109
Ultravist 300 200 ml: (S2) BOT1703110
Ultravist 300 500 ml: (S2) BOT1703111

Mauritius:
Ultravist 300 50ml: E12905/2017
Ultravist 300 100 ml: E12906/2017

Namibia:
Ultravist 300 20 ml: 90/28/026
Ultravist 300 50 ml: 90/28/027
Ultravist 300 75 ml: 04/28/1478
Ultravist 300 100 ml: 90/28/028
Ultravist 300 200 ml: 04/28/1479
Ultravist 300 500 ml: 04/28/1480
Ultravist 370 50 ml: 90/28/029
Ultravist 370 100 ml: 90/28/030
Ultravist 370 200 ml: 04/28/1481
Ultravist 370 500 ml: 04/28/1496

Zambia:
Ultravist 300
(50 ml and 100 ml):POM 140/015
Ultravist 370
(50 ml and 100 ml): POM 140/016

Zimbabwe:
Ultravist 300: PP 95/15.2/2983
Ultravist 370: PP 95/15.2/2984