SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

XENETIX 350 (350 mgI/ml) Solution for injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

	per ml	20 ml	50 ml	60 ml	75 ml	100 ml	150 ml	200 ml	500 ml
Iobitridol (INN)	767.8 mg	15.36 g	38.39 g	46.07 g	57.58 g	76.78 g	115.17 g	153.56 g	383.9 g
Iodine corresponding to	350 mg	7 g	17.5 g	21 g	26.25 g	35 g	52.5 g	70 g	175 g

Excipient with known effect: Sodium (up to 3.5 mg per 100 ml).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

Clear, colourless to pale yellow solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For adults and children undergoing:

. intravenous urography
. brain and whole-body CT
. intravenous digital subtraction angiography
. arteriography of the aorta and lower limbs
. angiocardiography
. sialography
. ERCP

This medicinal product is for diagnostic use only.

4.2 Posology and method of administration

The dosage may vary depending on the type of examination, the age, weight, cardiac output and general condition of the patient and the technique used. Usually the same iodine concentration and volume are used as with other iodinated X-ray contrast in current use. As with all contrast media, the lowest dose necessary to obtain adequate visualisation should be used.

Adequate hydration should be assured before and after administration as for other contrast media.

As a guideline, the recommended dosages are as follows:

Indications	Recommended dosage	
Intravenous urography (in adults)	Minimum dose: 1 ml/kg. It may be necessary to increase the dose in individual cases e.g. obesity or impaired renal function.	
Brain CT	Adults	1-1.5 ml/kg
Whole-body CT	Adults	The 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. Infusion is preferable for slow scanners and injection (bolus) for fast scanners. A dose of 3 ml/kg is usually considered as a maximum dose.
Brain and whole-body CT	Children	1.2-2.4 ml/kg
Intravenous digital subtraction angiography	Mean dose: 2.1 ml/kg	Min/max dose: 1.2-3.2 ml/kg
Peripheral angiography	Adults	10-90 ml (max: 250 ml)
Visceral angiography	Adults	12-60 ml (max: 250 ml)
Aortography	Adults	10-80 ml (max: 250 ml)
Renal angiography	Adults	6-15 ml (max : 250 ml)
Angiocardiography Left ventricle and aortic root inj.	Adults	30-60 ml/inj.
Angiocardiography Selective coronary arteriography	Adults	4-8 ml/inj.
Angiocardiography	Children	Depending upon age, weight and pathology
Sialography	0.5-1 ml	
ERCP	20-50 ml	

Usually, the rate of administration varies between 0.5 and 5 ml/s depending on the type of examination.

4.3 Contraindications

- Hypersensitivity to iobitridol or to any of the excipients;
- History of major immediate or delayed cutaneous reaction (see sections 4.4 and 4.8) to Iobitridol injection;
- Manifest thyrotoxicosis.

Carotid arteriography must be considered as a contra-indication for Xenetix 350.

4.4 Special warnings and precautions for use

Risk of allergy exists, regardless of the route of administration and the dose.

4.4.1. General particulars

4.4.1.1 Special warnings

In the absence of any specific studies, myelography is not an indication for Xenetix.

All iodinated contrast media can cause minor or major reactions that can be life- threatening. These can occur immediately (within 60 minutes) or be delayed (within 7 days) and are often unpredictable.

Due to risk of major reactions, emergency resuscitation equipment should be available for immediate use.

As in the case of all iodinated contrast agents, non-ionic water-soluble tri-iodinated contrast media can result in minor, severe, or fatal intolerance reactions, anaphylaxis or other manifestations of hypersensitivity which are often early and sometimes delayed. They are unpredictable but are more frequent in patients with a history of allergy (hives, asthma, hay fever, eczema, various food or drug allergies) or who have shown particular sensitivity during a previous examination with an iodinated contrast agent. They cannot be screened using iodine reaction tests or any other currently available test.

Patients who have already experienced a reaction after previous administration of an iodinated contrast agent present an increased risk of experiencing a further reaction following administration of the same or possibly another iodinated contrast agent, and are thus considered to be at-risk patients.

Non-ionic contrast media show extremely low interference with normal physiological functions. As a consequence, non-ionic contrast media have less anti-coagulant activity in vitro than ionic contrast media. Therefore, the period of contact between blood and contrast media in syringes and catheters should be kept as short as possible and close attention should be paid to the angiographic technique and catheter flushing with physiological saline (if necessary with heparin added) so as to minimise the risk of procedure-related thrombosis and embolism.

Iodinated contrast agents and the thyroid (see also 4.4.1.2.5 Dysthyroidism)

Before the administration of iodinated contrast agents, it is important to ensure that the patient is not due to undergo a scintigraphic or biological examination

of the thyroid or to receive radioactive iodine for therapeutic purposes.

Regardless of the route of administration, the administration of iodinated contrast agents disrupts hormone concentrations and the uptake of iodine by the thyroid or thyroid cancer metastases, until urine iodine levels have returned to normal.

Other Warnings

Extravasation is a non exceptional complication (0.04% to 0.9%) of intravenous injections of contrast media. This occurs more frequently with the high osmolar products, most of the injuries are minor, however severe injuries such as skin ulceration, tissue necrosis, and compartment syndrome may occur with any iodinated contrast medium. The risk and/or severity factors are patient-related (poor or fragile vascular conditions), and technique-related (use of a power injector, large volume). It is important to identify these factors, optimize the injection site and technique accordingly, and monitor the injection prior to, during and after the injection of Xenetix.

4.4.1.2. Precautions for use

Any severe disorder of water or electrolyte balance should be corrected, especially in patients with multiple myeloma, polyuria, oliguria, hyperuricemia, as well as in small children and elderly patients. Adequate hydration must be ensured before the examination.

4.4.1.2.1 Intolerance to iodinated contrast agents:

Prior to the examination:

- Identify at-risk patients by thorough screening of clinical history.

Corticosteroids and antihistamines H1 have been proposed for pre-medication in patients presenting with the highest risk of reaction to contrast media (known intolerance to an iodinated contrast agent). These drugs may not, however, protect from the occurrence of severe or fatal anaphylactic shock.

During the procedure the following measures must be taken:

  - Medical surveillance;
  - In situ venous access. After the procedure:

- After administration of the contrast agent, the patient must be monitored for at least 30 minutes since the majority of serious undesirable effects occur within this period of time.
- The patient must be informed about the potential for delayed reactions (up to 7 days after the examination) (see section 4.8).
- **Severe cutaneous adverse reactions**

  Severe cutaneous adverse reactions (SCARs) such as drug reaction/rash with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (Lyell's syndrome or TEN) and acute generalised exanthematous pustulosis (AGEP), which can be

life-threatening, have been reported in patients administered Xenetix (see section 4.8). At the time of initiation patients should be advised of the signs and symptoms and monitored closely for severe skin reactions. Xenetix should be discontinued immediately upon suspicion of a severe hypersensitivity reaction. If the patient has developed a severe cutaneous adverse reaction with the use of Xenetix, Xenetix must not be re-administered in this patient at any time (see section 4.3).

4.4.1.2.2 Renal insufficiency

Iodinated contrast agents can induce a transient alteration in renal function or worsen pre-existing renal insufficiency. Preventive measures include:

- Identifying at-risk patients, i.e. those with dehydration, renal insufficiency, diabetes, severe heart failure, monoclonal gammapathy (multiple myeloma, Waldenström's disease), history of renal failure after contrast agent administration; infants below the age of one year and elderly subjects with atheroma.
- Hydrate when necessary using a saline solution.
- Avoid concomitant use of nephrotoxic drugs. If this cannot be avoided, reinforce monitoring of renal laboratory parameters. [Includes aminosides, organoplatinum compounds, high-dose methotrexate, pentamidine, foscarnet and certain antivirals (aciclovir, ganciclovir, valaciclovir, adefovir, cidofovir, tenofovir), vancomycin, amphotericin B, immunosuppressants such ciclosporin or tacrolimus, ifosfamide.]
- Allow at least 48 hours between two radiological examinations with injection of contrast agents, or postpone any new examination until renal function returns to baseline.
- Prevent lactic acidosis in diabetics treated with metformin, by monitoring serum creatinine levels. Normal renal function: treatment with metformin must be suspended before contrast agent injection and for at least 48 hours after or until normal renal function is restored. Abnormal renal function: metformin is contraindicated. In case of emergency: if the examination is mandatory, precautions must be taken, i.e. metformin discontinuation, hydration, monitoring of renal function and checking for signs of lactic acidosis.

Iodinated contrast agents can be used in haemodialysed patients as the agents are removed by dialysis. Prior approval should be obtained from the haemodialysis department.

4.4.1.2.3 Hepatic insufficiency

Particular attention is necessary when a patient presents with both hepatic and renal insufficiency since, in this situation, the risk for retention of the contrast agent is increased.

Care should be taken in renal or hepatic impairment, diabetes or in patients with sickle cell disease.

Adequate hydration should be ensured in all patients before and after contrast

media administration and particularly in patients with renal impairment or diabetes where it is important to maintain hydration to minimise deterioration in renal function.

4.4.1.2.4 Asthma

Stabilisation of asthma is recommended before the injection of an iodinated contrast agent.

Due to an increased risk of bronchospasm, special caution should be taken in patients who have suffered an asthma attack within eight days preceding the examination.

4.4.1.2.5 Dysthyroidism

After iodinated contrast agent injection, particularly in patients with a goitre or a history of dysthyroidism, there is a risk of either a flare-up of hyperthyroidism or development of hypothyroidism. There is also a risk of hypothyroidism in neonates who have received or whose mother has received an iodinated contrast medium. Therefore, thyroid function such in neonates should be evaluated and closely monitored to ensure thyroid function is normal.

4.4.1.2.6 Cardiovascular disease (See section 4.8 Undesirable effects)

In patients with cardiovascular disease (such as early or patent heart failure, coronaropathy, pulmonary hypertension, valvulopathy, cardiac arrhythmias), the risk of cardiovascular reactions is increased after administration of an iodinated contrast agent. Intravasal injection of the contrast medium may cause pulmonary oedema in patients with manifest or incipient heart failure, whereas administration in pulmonary hypertension and heart valve disorders may result in marked changes in haemodynamics. The frequency and degree of severity appear related to the severity of the cardiac disorders. In case of severe and chronic hypertension, the risk of renal damage due to administration of the contrast medium and also due to the catheterisation itself may be increased. Ischaemic ECG changes and severe rhythm disorders are most frequently observed in elderly and heart disease patients. Very rare cases of ventricular fibrillation which occurred immediately after administration of the contrast medium have been reported outside the context of hypersensitivity reactions.

A careful evaluation of the risk-benefit ratio is necessary in these patients.

4.4.1.2.7 Central nervous system disorders

The benefit-to-risk ratio must be evaluated in each case:

- due to the risk of aggravation of neurological symptoms in patients with a transient ischaemic attack, acute cerebral infarct, recent intracranial haemorrhage, cerebral oedema, or idiopathic or secondary (tumour, scar) epilepsy.
- if the intra-arterial route is used in an alcoholic patient (acute or chronic alcoholism) and other drug-addicted subject.

Encephalopathy has been reported with the use of iobitridol (see section 4.8). Contrast- induced encephalopathy may manifest with symptoms and signs of neurological dysfunction such as headache, visual disturbance, cortical blindness, confusion, seizures, loss of coordination, hemiparesis, aphasia, unconsciousness, coma, and cerebral oedema. Symptoms usually occur within minutes to hours after administration of iobitridol and generally resolve within days.

Factors which increase blood-brain barrier permeability facilitate the passage of the contrast medium into cerebral tissue, which can lead to central nervous system reactions, e.g. encephalopathy. If contrast encephalopathy is suspected, appropriate medical management should be initiated and iobitridol should not be readministered.

4.4.1.2.8 Pheochromocytoma

Patients with pheochromocytoma can develop a hypertensive crisis after intravascular administration of the contrast agent and must be monitored prior to the examination.

4.4.1.2.9 Myasthenia gravis

Administration of a contrast agent can worsen the symptoms of myasthenia gravis.

4.4.1.2.10 Intensification of undesirable effects

Undesirable effects linked to contrast agent administration may be intensified in patients showing pronounced agitation, anxiety or pain. Appropriate management such as sedation may be necessary.

4.4.1.2.11 Paediatric population

Hypothyroidism or transient thyroid suppression may be observed after exposure to iodinated contrast media.

This adverse reaction may also be observed in newborns whose mothers have received an iodinated contrast medium during pregnancy (see section 4.6).

The incidence of hypothyroidism in patients younger than 3 years of age exposed to iodinated contrast media ranges between 1% and 15% depending on the age of the subjects and the dose of the iodinated contrast agent and is more commonly observed in neonates and premature infants.

Younger age, very low birth weight, prematurity, and the presence of other conditions, such as, admission to neonatal or paediatric intensive care units, and cardiac conditions are associated with an increased risk.

Paediatric patients with cardiac conditions may be at the greatest risk given that they often require high doses of contrast during invasive cardiac procedures, such as catheterization, and computed tomography (CT).

Special attention should be paid to paediatric patients below 3 years of age because an incident underactive thyroid during early life may be harmful for motor, hearing, and cognitive development and may require transient thyroxin (T4) replacement therapy.

Thyroid function should be evaluated in all paediatric patients after exposure to iodinated contrast media, especially in premature infants and neonates. If hypothyroidism is detected, thyroid function should be monitored as appropriate even when replacement treatment is given.

4.4.2 Warnings and precautions for use specific to ERCP

In case of ERCP there is a potential risk of pancreatitis and/or increase in amylase and lipase blood levels post-examination.

Warning about excipients

This medicinal product contains less than 1 mmol sodium (23 mg) per 100 ml, i.e. is essentially “sodium-free”.

4.5 Interaction with other medicinal products and other forms of interaction

4.5.1. Medicinal products

- **Metformin in diabetics** (see Section 4.4 Precautions for use — renal insufficiency).
- **Radiopharmaceuticals** (see section 4.4 Special warnings and precaution for use)

  Iodinated contrast media may affect the uptake of radioactive iodine by the thyroid for several weeks. This may lead to impaired uptake in thyroid scintigraphy, and/or to a decrease in the efficacy of Iodine 131 treatment. In patients due to undergo renal scintigraphy with injection of a radiopharmaceutical secreted by the renal tubule, it is preferable to carry out this examination before an iodinated contrast agent injection.
- **Beta-blocking agents vasoactive substances, angiotensin-converting enzyme inhibitors, angiotensin receptor antagonists.**

  There is some evidence to suggest that concurrent use of a beta blocker is a risk factor for anaphylactoid reactions; also, hypotensive effects may be exacerbated. Moreover these drugs reduce the efficacy of the cardiovascular compensation mechanism that occurs during haemodynamic disorders. The physician must be informed about the situation and appropriate intensive care equipment must be available.
- **Diuretics**

  Diuretics: in cases of dehydration induced by diuretics, there is an increased risk of acute renal failure, especially when using high doses of iodinated contrast media.

  The patient should be rehydrated before administration of an iodinated contrast medium.
- **Interleukin-2**

The risk of developing a reaction to the contrast agents is increased in the event of recent treatment with interleukin 2 (intravenous route): a skin reaction is possible, or more rarely hypotension, oliguria or even renal insufficiency.

4.5.2. Other forms of interaction

High concentrations of iodinated contrast media in plasma and urine can interfere with the in vitro determination of bilirubin, proteins and inorganic substances (iron, copper, calcium and phosphate); it is recommended that these determinations not be made within the first 24 hours following the examination.

4.6 Fertility, pregnancy and lactation

Pregnancy

In the absence of any teratogenic effects in animal species, no malformative effect is expected in humans (see section 5.3).

The transient iodine overload following administration to the mother may induce foetal dysthyroidism if the examination takes place after more than 14 weeks of amenorrhoea. However, in view of the reversibility of the effect and expected benefit to the mother, the isolated administration of an iodinated contrast agent is justifiable if the indication for the radiological examination in a pregnant woman has been carefully evaluated.

Thyroid function of neonates should be closely monitored if the iodinated contrast agent was administered to the mother during pregnancy (see section 4.4).

The product was not found to be mutagenic under the test conditions used.

However, X-ray exposure during pregnancy should be avoided whenever possible.

Breast-feeding

Iodinated contrast agents are only excreted in breast milk in very small amounts. Consequently, isolated administration to the mother involves a minor risk of adverse reactions in the infant. It is advisable to stop breastfeeding for 24 hours after administration of the iodinated contrast agent.

Fertility
No data on reproductive function is available.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

During clinical studies on 905 patients, 11% of patients experienced an adverse reaction related to administration of Xenetix (out of feeling of warmth), the most common being pain, injection site pain, bad taste, and nausea.

Adverse reactions related to the use of Xenetix are generally mild to moderate, and transient. The adverse reactions most commonly reported since marketing are feeling of warmth, and pain and oedema at the injection site.

The hypersensitivity reactions are usually immediate (during the injection or over the hour following the start of the injection) or sometimes delayed (one hour to several days after the injection), and then appear in the form of adverse skin reactions.

Immediate reactions comprise one or several, successive or concomitant effects, usually including skin reactions, respiratory and/or cardiovascular disorders, which may be the first signs of shock, which can rarely be fatal.

Severe rhythm disorders including ventricular fibrillation have been very rarely reported in heart disease patients, in as well as out of a context of hypersensitivity (see section 4.4 Precaution for use).

The adverse reactions are listed in the table below by SOC (System Organ Class) and by frequency with the following guidelines: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1 000 to <1/100), rare (≥1/10 000 to <1/1 000), very rare (<1/10 000), not known (cannot be estimated from the available data). The frequencies presented are derived from the data of an observational study on 352,255 patients.

System Organ Class	**Frequency: adverse reaction**
Immune system disorders	Rare: hypersensitivity Very rare: anaphylactic shock, anaphylactic reaction, anaphylactoid reaction
Endocrine disorders	Very rare: thyroid disorder Not known: transient neonatal hypothyroidism, hypothyroidism***
Nervous system disorders	Rare: presyncope (vasovagal reaction), tremor*, paresthesia* Very rare: coma*, seizure*, confusional state*, visual pathway disorders*, amnesia*, photophobia*, blindness transient*, somnolence*, agitation*, restlessness*, headache Not known: contrast encephalopathy****
Ear and labyrinth disorders	Rare: vertigo Very rare: hypoacusis
Cardiac disorders	Rare: tachycardia, bradycardia Very rare: cardiac arrest, myocardial infarction (more frequent after intracoronary injection), arrhythmia, ventricular fibrillation, angina pectoris, Torsades de Pointes, arteriospasm coronary Not known: dizziness**, cyanosis**
Vascular disorders	Rare: hypotension, hypertension Very rare: circulatory collapse
Respiratory, thoracic and mediastinal disorders	Rare: dyspnoea, cough, throat tightness, sneezing Very rare: respiratory arrest, pulmonary oedema, laryngospasm, bronchospasm, laryngeal oedema

Gastrointestinal disorders	Uncommon: nausea Rare: vomiting Very rare: abdominal pain
Skin and subcutaneous tissue disorders	Rare: angioedema, urticaria (localised or extensive), erythema, pruritus Very rare: Acute Generalized Exanthematous Pustulosis, Stevens-Johnson syndrome, Toxic Epidermal Necrolysis, eczema, rash maculo-papular (all as delayed hypersensitivity reactions) (see section 4.4) Not known: Drug reaction with eosinophilia and systemic symptoms (DRESS) (see section 4.4)
Renal and urinary disorders	Very rare: acute kidney injury, anuria
General disorders and administration site conditions	Uncommon: feeling hot Rare: face oedema, malaise, chills, injection site pain Very rare: injection site necrosis following extravasation, injection site inflammation following extravasation, injection site oedema
Investigations	Very rare: blood creatinine increased

* Examinations during which the iodinated contrast agent concentration in cerebral arterial blood is high.

** More often reported in a context of hypersensitivity reaction.

*** Paediatric population: Thyroid dysfunction was observed in paediatric patients 0 to 3 years of age following the administration of iodinated contrast agents.

**** Contrast encephalopathy may manifest with symptoms and signs described in section 4.4.

Compartment syndrome may be observed following extravasation as described in section 4.4.

The following adverse reactions were reported for other water-soluble iodinated contrast agents.

System Organ Class	**Frequency: adverse reaction**
Nervous system disorders	Paralysis, paresis, speech disorder
Psychiatric disorders	Hallucination
Gastrointestinal disorders	Pancreatitis acute (after ERCP), abdominal pain, diarrhoea, parotid gland enlargement, salivary hypersecretion, dysgeusia
Skin and subcutaneous tissue disorders	Erythema multiforme
General disorders and administration site conditions	Thrombophlebitis

Investigations	Electroencephalogram abnormal, blood amylase increased

Cardiovascular collapse of variable severity may occur immediately with no warning signs, or may complicate the cardiovascular manifestations mentioned in the above table.

Abdominal pain associated with diarrhoea, not reported for Xenetix, is linked mainly to administration via the oral or rectal route.

Local pain and oedema may occur at the injection site without extravasation of the injected product and are benign and transient.

During intra-arterial administration, the sensation of pain at the injection site depends on the osmolality of the product injected.

Articular pain with arthrography.

Pelvic pain with hysterosalpingography.

Paediatric population

The expected nature of the undesirable effects connected with Xenetix is the same as that of the effects reported in adults. Their frequency cannot be estimated from the available data.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

If a very high dose of contrast agent is administered, the water and electrolyte loss must be compensated by suitable rehydration. Renal function must be monitored for at least three days. Haemodialysis may be performed if necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Xenetix 350 is a non-ionic, water-soluble, tri-iodinated low osmolality contrast medium for urographic and angiographic examinations. The iobitridol molecule is characterised by its balanced and stable hydrophilicity.

Iodine content: 350 mgI/ml

Osmolality: 915 mOsm/kg
Viscosity at 37ºC: 10 mPa.s

Investigation of overall safety in terms of haemodynamic, cardiovascular, bronchopulmonary, renal, neurological and rheological parameters has demonstrated that the profile of iobitridol coincides with those of other non- ionic water-soluble tri-iodinated low-osmolality contrast media.

5.2. Pharmacokinetic Properties

Injected via the intravascular route, iobitridol is distributed in the vascular system and interstitial space. It is rapidly eliminated via urinary excretion (glomerular filtration without tubular reabsorption or secretion) in unchanged form.

5.3 Preclinical safety data

Toxicological studies using the intravenous route have revealed no effects except under conditions differing considerably from those used clinically (doses, repetition). In the case of iobitridol, as for all water-soluble non-ionic tri-iodinated contrast agents administered in large-volume (25 to 50 ml/kg) single doses, these effects occur as transient signs of hypothermia, respiratory depression or dose-dependent histological signs in the target organs (liver, kidneys) such as hepatocellular vacuolization and tubular ectasia. Repeated-dose administration in dogs for 28 days in large doses (8 ml/kg) resulted in granular and vacuolar tubular degeneration which was reversible following discontinuation of treatment.

Local irritation may be observed in cases of perivascular infiltration. The substance was not found to be mutagenic under the conditions of the tests used. Animal studies showed no teratogenic effects. In a rat fertility study there were no adverse effects on mating performance and fertility of animals.

In cases of renal failure, heterotopic excretion occurs via the biliary route. Iobitridol can be dialysed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium calcium edetate, trometamol hydrochloride, trometamol, hydrochloric acid or sodium hydroxide (for pH adjustment), water for injection.

6.2. Incompatibilities

To avoid any risk of incompatibility, no other medication should be injected in the same syringe.

6.3. Shelf life

Three years.

6.4. Special precautions for storage

Bottles: Keep the container in the outer carton; do not store above 30°C.
Bags: Keep the container in the outer carton.

6.5 Nature and contents of container

- Type II glass vial with chlorobutyl rubber stopper. Xenetix 350 is presented in the following container sizes:
  - 20 ml filled in a 20 or 30 ml vial
  - 50 ml filled in a 60 ml vial
  - 60 ml filled in a 60 ml vial
  - 75 ml filled in a 100 or 125 ml vial
  - 100 ml filled in a 100 or 125 ml vial
  - 150 ml filled in a 250 ml vial
  - 200 ml filled in a 250 ml vial
  - 500 ml filled in a 500 ml vial.
- Plastic syringe (polypropylene-based).
- Plastic (polyurethane or ethylene copolymer tetrafluoroethylene) catheter.
- Plastic (polyvinyl chloride) extension set.
- Polypropylene bag (100 ml, 150 ml, 200 ml and 500 ml).

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Special precautions for the use of 500 ml container:

It is recommended that the contrast medium be extracted after piercing the stopper once with an appropriate device.

The instructions for use provided by the manufacturers of all disposable materials used must be followed.

At the end of the day, any unused product or waste material should be disposed of in accordance with local requirements.

Other presentations: for single use only. Any content remaining should be discarded.

7. MARKETING AUTHORISATION HOLDER

Guerbet
B.P. 57400
F-95943 Roissy CdG Cedex
FRANCE

8. MARKETING AUTHORISATION NUMBER(S)

PL 12308/0011

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

04/10/2002

10 DATE OF REVISION OF THE TEXT

15/04/2025