XENETIX®
SOLUTION FOR INJECTION

PACKAGE INSERT

NAME OF THE MEDICINAL PRODUCT

XENETIX 300-50ML SOLN FOR INTRAVASCULAR, INTRAUTERINE AND INTRA-ARTICULAR INJ
XENETIX 300-100ML SOLN FOR INTRAVASCULAR, INTRAUTERINE AND INTRA-ARTICULAR INJ
XENETIX 350-50ML SOLN FOR INTRAVASCULAR INJ
XENETIX 350-100ML SOLN FOR INTRAVASCULAR INJ

QUALITATIVE AND QUANTITATIVE COMPOSITION

Iobitridol
Excipient: sodium calcium edetate, trometamol, trometamol hydrochloride, sodium hydroxide or hydrochloric acid, water for injection.

Each 100 mL of Xenetix 300 solution contains: Iobitridol ……65.81 g (658.1 mg/mL) Corresponding mass of iodine ……30 g (300 mg/mL)	
• Iodine content per mL: 300 mg • Viscosity at 20°C: 11 mPa.s • Viscosity at 37°C: 6 mPa.s • Osmolality: 695 mOsm/kg H2O	• Iodine quantity per 50 mL vial: 15 g • Iodine quantity per 100 mL vial: 30 g
Each 100 mL of Xenetix 350 solution contains: Iobitridol ……76.78 g (767.8 mg/mL) corresponding mass of iodine ……..35 g (350 mg/mL)	
• Iodine content per mL: 350 mg • Viscosity at 20°C: 21 mPa.s • Viscosity at 37°C: 10 mPa.s • Osmolality: 915 mOsm/kg H2O	• Iodine quantity per 50 mL vial: 17.5 g • Iodine quantity per 100 mL vial: 35 g

Excipient with known effect: sodium (up to 3.5 mg per 100 mL).

For the full list of excipients, see Section *List of excipients*.

PHARMACEUTICAL FORM

Solution for Injection

CLINICAL PARTICULARS

Therapeutic indications

This medicinal product is for diagnostic use only.

Xenetix® 300	Xenetix® 350
Contrast medium for use in:	
- Intravenous urography - Brain and whole body computed tomography - Intravenous digital subtraction angiography - Arteriography - Angiocardiography - Arthrography - Hysterosalpingography	- Intravenous urography - Brain and whole body computed tomography - Intravenous digital subtraction angiography - Arteriography - Angiocardiography

Note: Arthrography and Hysterosalpingography is indicated for Xenetix® 300 use only.

Posology and method of administration
Posology
The doses must be adapted to the examination and the regions to be opacified, as well as to the body weight and renal function of the subject, especially in children.

Xenetix® 300
Recommended mean dosages for intravascular routes:

Indications	Mean dose (mL/kg)	Total volume range (mL)
Urography with: - rapid i.v. injection - slow i.v. injection	 1.2 1.6	 50-100 100
CT: - cranial - whole body	 1.4 1.9	 20-100 20-150
Intravenous digital subtraction angiography	1.7	40-270
Arteriography: - cerebral - lower limbs	 1.8 2.8	 42-210 85-300
Angiocardiography	1.1	70-125

Recommended mean dosages for intracavitary routes:

Indications	Mean volume (mL)	Comments
Arthrography	5 to 20	Volume adapted to the joint
Hysterosalpingography	5 to 20	Adapted to the uterine volume

Xenetix® 350
Recommended mean dosages:

Indications	Mean dose (mL/kg)	Total volume range (mL)
Intravenous urography	1.0	50-100
CT: - cranial - whole body	 1.0 1.8	 40-100 90-180
Intravenous digital subtraction angiography	2.1	95-250
Arteriography: - peripheral - lower limbs - abdominal	 2.2 1.8 3.6	 105-205 80-190 155-330
Angiocardiography: - adults - children	 1.9 4.6	 65-270 10-130

Method of administration
Xenetix 300 is used by intravascular, intrauterine and intra-articular route and in single-dose form for presentations 50 and 100 mL.
Xenetix 350 is used by intravascular route and in single-dose form for presentations 50 and 100 mL

Contraindications

- Hypersensitivity to iobitridol or any of the excipients listed in Section *List of excipients.*
- History of a major immediate reaction or delayed skin reaction (see Section *Special warnings and special precautions for use* and Section *Undesirable effects*) to a Xenetix injection.
- Manifest thyrotoxicosis.
- Hysterosalpingography during pregnancy (Xenetix 300).

Special warnings and special precautions for use

- There is a risk of allergic reactions regardless of the route of administration or the dose.
- The risk of intolerance associated with products administered locally for opacification of body cavities is not clear-cut:

a) Administration via certain specific routes (articular, biliary, intrathecal, intra-uterine, etc.) results in varying degrees of systemic diffusion, i.e. systemic effects may be observed.

b) Oral or rectal administration normally results in very limited systemic diffusion. If the intestinal mucosa is normal, not more than 5% of the administered dose is found in urine and the rest is eliminated in faeces. Conversely, absorption is increased if the mucosa is damaged. In the event of perforation, this absorption is rapid and total with diffusion into the peritoneal cavity and the product is eliminated in urine. The occurrence of dose-dependent systemic effects is therefore dependent on the status of the intestinal mucosa.

c) However, the allergic immune mechanism is not dose-dependent and immuno-allergic reactions may occur at any time, regardless of the administration route.

Thus, in terms of the frequency and intensity of undesirable effects, there is a difference between:

- products administered via the vascular route and certain local routes, and
- products administered via the GI tract which are only slightly absorbed under normal conditions.

<u>General particulars corresponding to all iodinated contrast media</u>

<u>Warnings</u>

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

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

Because of the risk of major reactions, emergency resuscitation equipment should be available for immediate use.

Several mechanisms have been evoked to explain the occurrence of these reactions:

- direct toxicity affecting the vascular endothelium and tissue proteins.
- pharmacological action modifying the concentration of certain endogenous factors (histamine, complement factors, inflammation mediators), observed more frequently with hyperosmolar contrast media.
- immediate IgE-mediated allergic reactions to the contrast medium Xenetix (anaphylaxis)
- allergic reactions due to a cellular-type mechanism (delayed cutaneous reactions)

Patients who have already experienced a reaction during administration of an iodinated contrast medium are at higher risk of experiencing another reaction following administration of the same or possibly a different iodinated contrast medium, and are thus considered to be at-risk patients.

Iodinated contrast media and the thyroid (see also *Section Dysthyroidism*)

Before administering an iodinated contrast medium, it is important to ensure that the patient is not scheduled to undergo a scintigraphic examination or laboratory tests related to the thyroid or to receive radioactive iodine for therapeutic purposes.

Administration of contrast media via any route disrupts hormone concentrations and iodine uptake by the thyroid or by metastases of thyroid cancer, until urine iodine levels have returned to normal.

Other warnings

Extravasation is an uncommon complication (0.04% to 0.9%) of intravenous injections of contrast media. More common with the high-osmolar contrast media, most lesions are minor, however severe lesions 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 syringe pump, 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.

Precautions for use

Intolerance to iodinated contrast media:

Prior to the examination:

- Identify at-risk patients by a precise screening of histories.

Corticosteroids and H1-type antihistamines have been suggested as premedication in patients presenting with the highest risk for intolerance reactions (history of intolerance to an iodinated contrast medium). However, they do not prevent the occurrence of serious or fatal anaphylactic shock. During the procedure, the following measures must be maintained:

- Medical surveillance
- Permanent venous access

After the examination:

- After administration of the contrast medium, the patient must be monitored for at least 30 minutes, since most serious adverse reactions occur within this time period.
- The patient must be informed of the possibility of delayed reactions (for up to seven days) (see Section *Undesirable effects*)

- Serious cutaneous adverse reactions
  Serious cutaneous adverse reactions (SCARs) such as drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), Lyell's syndrome (toxic epidermal necrolysis or TEN) and acute generalised exanthematous pustulosis (AGEP), which are potentially fatal, have been reported in patients having received Xenetix (see Section *Undesirable effects)*. When treatment starts, patients must be informed of the signs and symptoms and be monitored closely to detect any serious cutaneous reactions. Xenetix should be discontinued immediately in the event of a suspected serious hypersensitivity reaction. In the event of a serious cutaneous adverse reaction in a patient using Xenetix, Xenetix must not be re-administered to that patient under any circumstances (see Section *Contraindicatoins*).

Renal impairment

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

- Identify at-risk patients, i.e. with dehydration or renal insufficiency, diabetes, severe heart failure, monoclonal gammapathy (multiple myeloma, Waldenstrom's macroglobulinemia), a history of renal impairment after iodinated contrast medium administration, children under one year of age and elderly subjects with atheroma.
- Hydrate when necessary using a saline solution.
- Avoid combinations with nephrotoxic medicines. If this cannot be avoided, laboratory monitoring of renal function must be intensified. The medicines concerned include aminoglycosides, organoplatinum compounds, high doses of methotrexate, pentamidine, foscarnet and certain antiviral media [aciclovir, ganciclovir, valaciclovir, adefovir, cidofovir, tenofovir], vancomycin, amphotericin B, immunosuppressants such as cyclosporine or tacrolimus, ifosfamide)
- Allow at least 48 hours between radiological examinations with injection of contrast media, 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 medium 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 media can be used in haemodialysed patients as the media are removed by dialysis. Prior approval should be obtained from the haemodialysis department.

Hepatic impairment

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

Care should be taken in case of 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.

Asthma

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

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

Dysthyroidism

After iodinated contrast medium injection, particularly in patients with a goitre or a history of dysthyroidism, there is a risk either of 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.

Consequently, thyroid function in neonates must be evaluated and closely monitored to check that it is normal

Thyroid dysfunction characterized by hypothyroidism or transient thyroid suppression has been

reported in pediatric patients 0-3 years of age after exposed to iodinated contrast media. Younger age, very low birth weight, prematurity and other conditions are associated with an increased risk. If thyroid dysfunction is detected, treat and monitor thyroid function as clinically needed.

Cardiovascular diseases (see Section Undesirable effects)

In patients with cardiovascular disease (such as early or manifest heart failure, coronaropathy, pulmonary hypertension, valvulopathy, cardiac arrhythmias), the risk of cardiovascular reactions is increased after administration of an iodinated contrast medium. Intravascular injection of the contrast medium may cause pulmonary oedema in patients with manifest or latent heart failure, whereas administration in cases of 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. The benefit/risk balance must be weighed carefully in such patients.

Central nervous system disorders

The benefit/risk balance must be evaluated for 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 patients.

Phaeochromocytoma

Patients with phaeochromocytoma may develop a hypertensive crisis after intravascular administration of a contrast medium and must be prepared accordingly prior to the examination.

Myasthenia

Administration of a contrast medium may worsen the symptoms of myasthenia gravis.

Intensification of side effects

Adverse reactions related to the administration of an iodinated contrast medium may be intensified in patients showing pronounced agitation, anxiety and pain. Appropriate management may be necessary, as far as sedation.

Excipients

This medicinal product contains sodium. It contains less than 1 mmol sodium per 100 mL, i.e. essentially “sodium-free”.

Paediatric population

Temporary suppression of the thyroid or hypothyroidism has been observed in children after exposure to iodine-based contrast agents. Following a diagnostic procedure, this was more commonly observed in neonates and preterm infants, as well as after procedures associated with higher doses. Neonates may also be exposed by maternal exposure (see section *Fertility, pregnancy and lactation*). For neonates, in particular preterm infants, who have been exposed to iobitridol, whether through the mother during pregnancy or during the neonatal period, it is recommended to monitor thyroid function. If hypothyroidism is detected, the need for treatment must be investigated, and thyroid function must be monitored until normalisation.

Warnings and precautions for use specific to certain administration routes with appreciable systemic diffusion (Xenetix 300)

Products administered via the intrauterine route

Contraindication

Pregnancy for hysterosalpingography.

Precautions for use

In the interview and with appropriate tests, systematically check for possible pregnancy in women of childbearing age. Exposure of the female genital routes to x-rays must be subject to careful evaluation of the benefit/risk balance.

In the event of inflammation or acute pelvic infection, hysterosalpingography can only be performed after a careful assessment of the benefit/risk balance.

Interaction with other medicinal products and other forms of interaction

Medicinal products

+ Metformin in diabetic patients(see Section *Precautions for use — renal insufficiency*).

+ Radiopharmaceuticals (see Section Warnings)
Iodinated contrast media alter the uptake of radioactive iodine by the thyroid for several weeks, which may on the one hand result in diminished uptake in thyroid scintigraphy and on the other hand decrease the efficacy of iodine-131 treatment.
In patients scheduled to undergo renal scintigraphy with injection of a radiopharmaceutical excreted by the renal tubules, it is preferable to carry out this examination before injecting the iodinated contrast medium.

+ Beta blockers, vasoactive substances, angiotensin-converting enzyme inhibitors, angiotensin receptor antagonists.
These medicinal products reduce the efficacy of the cardiovascular compensation mechanisms that occur in haemodynamic disorders. The physician must be aware of this before injecting the iodinated contrast medium, and appropriate resuscitation equipment must be available.

+ Diuretics

Due to the risk of dehydration provoked by diuretics, rehydration with water and electrolytes must be carried out prior to the examination in order to limit the risk of acute renal impairment.

+ Interleukin 2

The risk of developing a reaction to the contrast media is increased if the patient has recently been treated with interleukin-2 (intravenous route), i.e. rash or, more rarely, hypotension, oliguria, or even renal impairment.

Other forms of interaction

High concentrations of iodinated contrast media in plasma and urine may interfere with the in vitro determination of bilirubin, proteins and inorganic substances (iron, copper, calcium and phosphate). It is recommended that these determinations should not be carried out within 24 hours following the examination.

Fertility, pregnancy and lactation

Pregnancy
There are no or few data (fewer than 300 pregnancy outcomes) on the use of iobitridol in pregnant women.

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity

(see section *Preclinical safety data*).

As a precautionary measure, it is preferable to avoid the use of XENETIX during pregnancy.

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

In neonates exposed to iobitridol *in utero*, it is recommended to monitor thyroid function (see section *Special warnings and precautions for use*).

Lactation
Iodinated contrast agents are excreted in breast milk in very small amounts. Consequently, isolated administration to the mother involves a minor risk of undesirable effects in the infant. It is preferable to suspend breastfeeding for 24 hours after administration of the iodinated contrast agent.

Fertility
A study conducted on rats does not indicate any effects on reproductive function.

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

Undesirable effects related to the use of Xenetix are generally mild to moderate, and transient.

The adverse reactions most commonly reported during administration of Xenetix 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 cardiac rhythm disorders including ventricular fibrillation have been very rarely reported in heart disease patients and outside of a context of hypersensitivity (see Section *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 (≥1/1000 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, anaphylactoid reaction, anaphylactic reaction
Endocrine disorders	Very rare: thyroid disorders Not known: transient neonatal hypothyroidism, hypothyroidism***

Nervous system disorders	Rare: presyncope (vasovagal reaction), tremor*, paresthesia* Very rare: coma*, convulsions*, confusion*, visual disorders*, amnesia*, photophobia*, transient blindness*, somnolence*, agitation*,headache Not known: dizziness**
Ear and labyrinth disorders	Rare: dizziness Very rare: hearing disorders
Cardiac disorders	Rare: tachycardia, bradycardia Very rare: cardiac arrest, myocardial infarction (more frequent after intracoronary injection), arrhythmia, ventricular fibrillation, angina pectoris, torsades de pointes, coronary arteriospasm

Vascular disorders	Rare: arterial hypotension, arterial hypertension Very rare: circulatory collapse Not known: cyanosis**
Respiratory, thoracic and mediastinal disorders	Rare: dyspnoea, cough, throat tightness, sneezing Very rare: respiratory arrest, pulmonary oedema, bronchospasm, laryngospasm, laryngeal oedema
Gastrointestinal disorders	Uncommon: nausea Rare: vomiting Very rare: abdominal pain
Skin and subcutaneous tissue disorders	Rare: Angioneurotic oedema, urticaria (localised or extensive), erythema, pruritus Very rare: Acute generalised exanthematous pustulosis, Stevens-Johnson syndrome, toxic epidermal necrolysis, eczema, maculopapular rash (all as delayed hypersensitivity reactions) (see Section *Special warnings and special precautions for use*) Not known: Drug reaction with eosinophilia and systemic symptoms (DRESS) (see Section *Special warnings and special precautions for use*)
Renal and urinary disorders	Very rare: acute renal failure, anuria
General disorders and administration site conditions	Uncommon: feeling hot Rare: Facial oedema, malaise, chills, injection site pain Very rare: injection site necrosis following extravasation, injection site oedema, injection site inflammation following extravasation
Investigations	Very rare: blood creatinine increased

*Examinations during which the iodinated contrast medium concentration in arterial blood is high

** Effect reported most often in the context of a hypersensitivity reaction

*** Transient hypothyroidism has been reported in younger children after exposure to iodine-based contrast agents (See section *Special warnings and precautions for use*)

As described in Section *Special warnings and special precautions for use*, compartment syndrome may be seen following extravasation.

The following adverse reactions were reported for other water-soluble iodinated contrast media:

System Organ Class	**Frequency: adverse reaction**
Nervous system disorders	Paralysis, paresis, speech disorder
Psychiatric disorders	hallucinations
Gastrointestinal disorders	Acute pancreatitis (following ERP), Abdominal pain, diarrhoea, parotid gland enlargement, salivary hypersecretion, dysgeusia

Skin and subcutaneous tissue disorders	Erythema multiforme
Vascular disorders	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.

Adverse reactions related to specific examinations (Xenetix 300): Arthrography: arthralgias was commonly reported during clinical studies (4%).
Hysterosalpingography: pelvic pain was commonly reported during clinical studies (3%).

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 to the local Health Authority.

Overdose

If a very high dose of contrast medium 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.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic group : X-RAY IODINATED CONTRAST MEDIA

ATC code: V08AB11

Xenetix 300 is a urographic and angiographic water-soluble non-ionic contrast medium with an osmolality of 695 mOsm/kg.

Xenetix 350 is a urographic and angiographic water-soluble non-ionic contrast medium with an osmolality of 915 mOsm/kg.

Pharmacokinetic properties

After intravascular injection, iobitridol is distributed in the intravascular system and interstitial compartment. In humans, the elimination half-life is 1.8 h, the volume of distribution is 200 mL/kg and the total clearance is 93 mL/min (mean values). Binding to plasma proteins is negligible (< 2%). It is mainly eliminated via the kidneys (glomerular filtration without tubular reabsorption or secretion) in unchanged form. The osmotic diuresis induced by Xenetix is dependent on the osmolality and the volume injected.

In patients with renal impairment, elimination occurs mainly via the biliary route. The substance can be dialysed.

Preclinical safety data

Toxicology studies using the intravenous route did not reveal any effects, except under conditions that differ considerably from those used clinically (doses, repetitions). In the case of iobitridol, as with all tri-iodinated, non-ionic and water-soluble contrast agents administered in single large-volume doses (25-50 ml/kg), these effects manifest as transient signs of hypothermia, respiratory depression or dose-dependent histological signs in the target organs (liver, kidneys), such as hepatocellular vacuolisation and tubular ectasia. Repeated dose administration in dogs for 28 days at high doses (8 ml/kg) resulted in granular and vacuolar degeneration, which was reversible after discontinuation of treatment.

Local irritation may be observed in the event of perivascular infiltration. The substance was not found to be mutagenic under the test conditions used. Animal studies have shown no toxic effects on fertility, reproductive performance and embryofoetal development.

PHARMACEUTICAL PARTICULARS

List of excipients

Sodium calcium edetate, trometamol, trometamol hydrochloride, sodium hydroxide or hydrochloric acid, water for injection.

Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Shelf life

3 years.

Special precautions for storage

Do not store above 30°C, store protected from light.

Nature and content of container

MAL19992347AZ - Xenetix 300 50 mL type II glass vials/bottles with chlorobutyl rubber stoppers.
MAL19992348AZ - Xenetix 300 100 mL type II glass vials/bottles with chlorobutyl rubber stoppers.
MAL19992349AZ - Xenetix 350 50 mL type II glass vials/bottles with chlorobutyl rubber stoppers.
MAL19992350AZ - Xenetix 350 100 mL type II glass vials/bottles with chlorobutyl rubber stoppers.

Instructions for disposal and handling

No special requirements for disposal.

Name and address of manufacturer

GUERBET
BP57400
95943 Roissy CdG Cedex FRANCE
Located at
16-24 rue Jean Chaptal, 93600
Aulnay-sous-Bois, FRANCE

DATE OF REVISION

[Date of Approval]