Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Xenetix 350mg I/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 corresponding to Iodine	767.8 mg	15.36g	38.39g	46.07g	57.58g	76.78g	115.17g	153.56g	383.9g
	350 mg	7g	17.5g	21g	26.25g	35g	52.5g	70g	175g

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

This medicinal product is for diagnostic use only.

4.2 Posology and method of administration

Adults and Children:

The dosage may vary depending on the type of examination, the age, weight, cardiac output and general condition of the patient and the techniques used. As with all contrast media, the lowest dose necessary to obtain visualisation should be used. Adequate hydration should be assessed before and after administration.
The dosage guidelines are based on the dosages used in low molecular weight contrast media in current use, and on the dosages used during clinical trials with Xenetix.

As a guideline, the dosages observed during the clinical trials were as follows:

Indications	Recommended dosage	
Intravenous urography	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

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 skin reaction (see sections 4.4 and section 4.8) to Iobitridol injection;
- Manifest thyrotoxicosis;

4.4 Special warnings and precautions for use

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

1. 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.
2. 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 the absorption 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.

3. 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.

4.4.1 General comments for all iodinated contrast agents

4.4.1.1 Warnings

In the absence of specific studies, myelography is not an indication for Xenetix.
All iodinated contrast agents 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 reaction to the contrast agent XENETIX (anaphylaxis).
- Allergic reaction due to a cellular-type mechanism (delayed cutaneous reactions).

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

4.4.1.2 Iodinated contrast agents and the Thyroid (see also section Dysthyroidism)

Before administering an iodinated contrast agent, it is important to ensure that the patient is not scheduled to undergo a scintigraphic examination or laboratory test related to the thyroid or to receive radioactive iodine for therapeutic purposes. Administration of contrast agents, via any route, disrupts hormone concentrations and the iodine uptake by the thyroid or by metastases of thyroid cancer, until urine iodine levels have returned to normal.

4.4.1.3 Other Warnings

Extravasation is a non exceptional complication (0.04% to 0.9%) of intravenous injections of contrast media. More frequent 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.

4.4.2 Precautions for use

4.4.2.1 Intolerance to iodinated contrast agents:

Prior to the examination:

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

Corticosteroids and H1-type antihistamines have been suggested as pre-medication in patients presenting with the highest risk for intolerance reactions(history of intolerance to an iodinated contrast agent). 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 procedure:

- After administration of the contrast agent, 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 7 days) (see section 4.8, Undesirable effects). **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, Undesirable effects.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).

4.4.2.2 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. with dehydration or renal insufficiency, diabetes, severe heart failure, monoclonal gammapathy (multiple myeloma, Waldenström's macroglobulinemia), a history of renal failure after iodinated contrast agent 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 agents (aciclovir, ganciclovir, valaciclovir, adefovir, cidofovir, tenofovir), vancomycin, amphotericin B, immunosuppressants such as ciclosporine 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 diabetic patients treated with biguanide (i.e. metformin) according to blood creatinine level (see 4.5. Interactions - Antidiabetics in the biguanide group).

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.

4.4.2.3 Hepatic insufficiency

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

4.4.2.4 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 suffered an asthmatic attack within 8 days prior to the examination.

4.4.2.5 Dysthyroidism

After iodinated contrast agent 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 agent. Therefore, thyroid function in such neonates should be evaluated and closely monitored to ensure thyroid function is normal.

4.4.2.6 Cardiovascular diseases

In patients with cardiovascular disease (such as early or patent heart failure, coronaropathy, pulmonary hypertension, valvulopathy, cardiac arrhythmias), the risks 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 arrhythmias 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.
(See Section 4.8 Undesirable effects)

Careful weighing up of the risk-benefit ratio is necessary in these patients.

4.4.2.7 Central nervous system disorders
The benefit/risk ratio 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, idiopathic or secondary (tumour, scar) epilepsy.
- If the intra-arterial route is used in alcoholic patients (acute or chronic alcoholism), and other drug- addicted subjects.
- 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.

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

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

4.4.2.10 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

4.4.2.11 Paediatric population
Transient thyroid suppression or hypothyroidism has been observed in children after exposure to iodinated contrast media. Following a diagnostic procedure, this has been more frequently observed in neonates and premature infants and also following procedures associated with higher doses. Neonates may also be exposed via maternal exposure (see section 4.6). In neonates, especially preterm infants, who have been exposed to iobitridol, either through the mother during pregnancy or in the neonatal period, it is recommended to monitor thyroid function. If hypothyroidism is detected, the need for treatment should be considered and thyroid function should be monitored until normalised.

4.5 Interaction with other medicinal products and other forms of interaction

4.5.1 Medicinal products

Antidiabetics in the biguanide group (i.e. metformin) (see also section 4.4.2.2. Precautions for use – Renal insufficiency)

1. In patients with normal renal function, biguanide treatment can be continued normally.
2. In patients with moderate renal insufficiency (estimated glomerular filtration rate [eGFR] 30-59 mL/min/1.73m^2):
a. Patients receiving intravenous contrast medium with an eGFR equal to or greater than 45 mL/min/1.73 m^2 can continue to take the biguanide normally.

b. Patients receiving intra-arterial contrast medium, and those receiving intravenous contrast medium with an eGFR between 30 and 44 mL/min/1.73 m^2, should stop the biguanide 48 hours before contrast medium and should only restart the biguanide 48 hours after contrast medium if renal function has not deteriorated.
3. In patients with eGFR less than 30 mL/min/1.73 m2 (chronic kidney disease [CKD] 4 and 5), or with an intercurrent illness causing reduced liver function or hypoxia, the biguanide is contraindicated and a careful risk/benefit assessment should precede the administration of any iodinated contrast media.
4. Emergency patients. The biguanide should be stopped from the time of contrast medium administration. After the procedure, the patient should be monitored for signs of lactic acidosis. The biguanide should be restarted 48 hours after contrast medium if serum creatinine/eGFR is unchanged from the pre-imaging level.

Radiopharmaceuticals *(see section 4.4., Special warnings and Precautions 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. These drugs reduce the efficacy of the cardiovascular compensation mechanism that occurs during haemodynamic disorders. The physician must be informed before the injection and appropriate intensive care equipment must be available.
Diuretics
Due to the risk of dehydration caused by diuretics, hydroelectrolyte rehydration prior to the examination is necessary in order to minimise the risk of acute renal failure.
Interleukin-2
The risk of developing a reaction to the contrast agent is increased in the event of recent treatment with interleukin 2 (intravenous route): rash 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
There are no or limited amount of data (less than 300 pregnancy outcomes) from the use of iobitridol in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3).
As precautionary measure, it is preferable to avoid the use of Xenetix during pregnancy.

The transient 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 the 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 who have been exposed to iobitridol in utero, it is recommended to monitor thyroid function (see section 4.4).

Breastfeeding
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
Study on rats do not indicate effects on reproductive function.

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 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 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 (³1/10), common (³1/100 to 1<1/10), uncommon (³1/1000 to 1<1/100), rare (³1/10 000 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.

SystemOrganClass	**Frequency:adverse reaction**
Immune system disorders	Rare: hypersensitivity Very rare: anaphylactic shock, anaphylactic reaction, anaphylactoid reaction
Endocrine disorders	Very rare: thyroid disorder, Unknown: 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*, headache Unknown: dizziness**, 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
Vascular disorders	Rare: hypotension, hypertension Very rare: circulatory collapse Unknown: 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: 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

***Transient hypothyroidism has been reported in younger children following exposure to iodinated contrast media (see section 4.4)
****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 OrganClass	**Frequency:adversereaction**
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
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.

- Articular pain with arthrography.
- Pelvic pain with hysterosalpingography.

Paediatric population
The expected nature of the undesirable effects connected with Xenetix is similar to 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 the national reporting system:
HPRA Pharmacovigilance
Website: www.hpra.ie

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 (ATC code: V08AB11). The iobitridol molecule is characterised by its balanced and stable hydrophilicity.

Iodine content: 350 mg/ml

Osmolality: 915 mOsm/kg
Viscosity at 37°C 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.
In cases of renal failure, heterotopic excretion occurs via the biliary route. Iobitridol can be dialysed.

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, theseeffects occur as transient signs of hypothermia, respiratory depression or dose-dependent histological signs in the target organs (liver, kidney) 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 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 toxic effect on fertility, reproductive performance and embryo-foetal development.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium calcium edetate
Trometamol hydrochloride
Trometamol
Hydrochloric Acid (for pH adjustment)
Sodium Hydroxide (for pH adjustment)
Water for Injections

6.2 Incompatibilities

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

6.3 Shelf life

Unopened: 3 years
The product after opening should be used immediately and not stored.

6.4 Special precautions for storage

Keep the container in the outer carton in order to protect from light. Do not store above 30 °C.

6.5 Nature and contents of container

Type II colourless glass bottle (20ml, 50ml, 60ml, 75ml, 100ml, 150ml, 200ml, 500ml) with chlorbutyl rubber stopper.
Plastic syringe (polypropylene-based).
Plastic (polyvinyl chloride) butterfly-winged infusion set.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

For single use only. Discard any remaining contents.

Special precautions for the use of 500 mL container:
It is recommended that the contrast medium be extracted after piercing once the stopper 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.

7 MARKETING AUTHORISATION HOLDER

Guerbet
BP 57400
95943 Roissy CdG cedex
France

8 MARKETING AUTHORISATION NUMBER

PA0686/002/003

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