Note: The PL mockup is available in 3 dimensions: 420 x 200 mm for large vial presentations (> or = to 75mL) , 455 x 140mm for smaller vial presentations (< or = to 60 mL), and 420 x 140mm for softbag presentations.

Package leaflet: Information for the user

XENETIX 250 (250 mg I/mL), solution for injection
XENETIX 300 (300 mg I/mL), solution for injection
XENETIX 350 (350 mg I/mL), solution for injection

Iobitridol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effect, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

1. WHAT XENETIX IS AND WHAT IT IS USED FOR

Xenetix is a diagnostic agent. It belongs to the group of contrast agents used for radiological examinations.

Xenetix is used to enhance the contrast of the images obtained during radiological examinations. This contrast enhancement improves the visualisation and outline of certain body parts.

This medicine is for diagnostic use only.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE XENETIX

You should read the information in this section carefully.
You and your doctor should consider this information before you are given Xenetix.

Do not use Xenetix if:
- you are allergic to iobitridol or any of the other ingredients of Xenetix (listed in section 6)
- you have already had an allergic reaction following the injection of iobitridol (see section 4: possible side effects)
- you have excess thyroid hormones (these are hormones that affect your energy level)
- you are pregnant or think you are pregnant and are due to undergo hysterosalpingography (examination of the uterus and fallopian tubes)

Warnings and precautions
Inform your doctor if the following applies to you:
- you have previously had an allergic reaction to a contrast agent during an examination
- you are asthmatic and have had an asthma attack within the 8 days preceeding the examination
- you have a history of allergic reaction to anything
- you have sickle cell disease (an inherited blood disorder that affects red blood cells)
- you have any condition that could cause a water or electrolyte imbalance (for example dehydration, increase of sodium in your blood, which may change the amount of certain body salts, eg calcium, potassium, sodium… in your body)
- you are being treated with a beta-blocker (medicine for heart and blood pressure disorders)
- you have kidney problems
- you have liver disease
- you have pancreatitis
- you have a disease affecting your heart or your blood vessels
- you have had convulsions or you are being treated for epilepsy
- you have heart failure (your heart is not pumping well)
- you have diabetes
- you have had a stroke or recent history of intracranial haemorrhage (bleeding inside the skull)
- you have myasthenia gravis
- you have thyroid disorders or a history of thyroid disease
- you have a phaeochromocytoma (tumour of the adrenal gland)
- you have bone-marrow disease (monoclonal gammapathy: multiple myeloma or Waldenström's disease)
- you are due to undergo a thyroid examination in the near future or treatment with radioactive iodine
- you regularly drink large amounts of alcohol or you use drugs
- you have anxiety, nervousness or pain, as possible side-effects may be intensified.
- you have or have ever had inflammation in the pelvis affecting your womb, tubes or ovaries.

In all these cases, your doctor will only give you Xenetix if the benefits outweigh the risks. If you are given Xenetix, your doctor will take the precautions necessary and the administration of Xenetix will be carefully monitored.

Other medicines and Xenetix
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
In particular, please inform your doctor or pharmacist if:
- you are taking or have recently taken medicines for:
  - heart and blood pressure disorders such as beta-blockers or diuretics
  - diabetes (metformin)
- you have recently received interleukin-2 (a drug for treating cancer)

Xenetix with food and drink
There are no known interactions between Xenetix and food and drinks. However, please check with your doctor or pharmacist if it is required not to eat or drink before the examination.
You should inform your doctor if you regularly drink large quantities of alcohol (see section 2-Warnings and precautions).

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Xenetix may pass into your breast milk.

Driving and using machines
Xenetix is unlikely to affect your ability to drive or use machines.
If you feel unwell after the examination, you should not drive or use machines.

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

3. HOW TO USE XENETIX

Xenetix will be administered to you by injection.

During the examination, you will be under the supervision of a doctor. A plastic needle will be left in your vein; this will allow the doctor to inject you with appropriate emergency drugs if necessary. If you experience an allergic reaction, the administration of Xenetix will be stopped.

The procedure will be carried out in a hospital, clinic or private practice. The attending staff know what precautions have to be taken for the examination. They are also aware of any possible complications that can occur.

Dosage
Your doctor will determine the dose you will receive and supervise the injection.

If too much Xenetix has been administered to you
It is highly unlikely that you will be given an overdose. You will be given Xenetix in a medical setting by a trained person. In a real case of overdose, Xenetix can be removed from the body by haemodialysis (blood cleaning).

Speak to your doctor if you are unsure or worried.

If you have any further questions on the use of this product ask your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Xenetix can cause side effects, although not everybody gets them.

Most side effects occur during the injection or within the first hour following administration. Some effects can occur up to several days after Xenetix injection.

Side effects of Xenetix are generally mild to moderate and are temporary.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please also tell your doctor or pharmacist as soon as possible.

There is a small risk (rare) that you may have an allergic reaction to Xenetix. Such reactions can be severe and **exceptionally result in shock** (very rare case of allergic reaction that could put your life in danger).

Any of the symptoms listed below may be the first signs of shock. Immediately inform your doctor or health professional if you have any of them.

- swelling of the face, mouth or throat which may cause you difficulties in swallowing or breathing
- hypotension (low blood pressure)
- breathing difficulties
- wheezy breathing
- coughing
- itching
- runny nose
- sneezing
- skin rash
- urticaria (patches of red skin, severe itching)
- Stevens-Johnson syndrome or Lyell's syndrome (severe allergic skin reaction with blister like lesions)

Altogether, the side effects which have been described for Xenetix are the following:

Uncommon side effects (probably affecting fewer than 1 in 100 people)
- sensation of warmth
- nausea

Rare side effects (probably affecting fewer than 1 in 1,000 people)
- swelling of various parts of the body including the face
- tightness sensation in the throat
- hypotension (low blood pressure)
- breathing difficulties
- wheezy breathing
- coughing
- sneezing
- eye irritation
- vertigo (feeling of spinning or dizziness)
- malaise (feeling of discomfort or being unwell)
- vomiting
- tachycardia (fast heart rate)
- urticaria (patches of red skin, severe itching)
- other skin reaction
- injection site pain
- chill
- tremor
- presyncope (lightheaded)
- paresthesia (feeling of pins and needles in a limb)

Very rare side effects (probably affecting fewer than 1 in 10,000 people)
- thyroid disorder
- coma*
- convulsions (fits)*
- confusion*
- visual disorders*
- memory loss*
- photophobia (fear of light)*
- transient blindness*
- drowsiness*
- agitation*
- headache
- hearing difficulties
- cardiac arrest
- blood creatinine increased
- changes to heart rate, angina or heart attack (heavy chest pain radiating up left arm)
- circulatory failure
- myocardial infarction
- abdominal pain
- kidney disorders
- breathing difficulties caused by tightening of the muscles in your airways or water in the lungs
- swelling of throat
- eczema
- severe allergic skin reaction including reaction with blister like lesions

If Xenetix is accidentaly injected outside the vein, pain can occur around the site of injection with swelling, inflammation, local reddening or necrosis.

Other side effect (frequency undertermined on the basis of the available data):
- joint pain (when Xenetix is administered into joints)
- pelvic pain (when Xenetix is administered into the uterus and fallopian tubes)
- high blood pressure (hypertension)
- abnormal heartbeats may occur (torsades de pointes)
- temporary discomfort or pain that is caused by a temporary spasm (constriction) in one or more of your coronary arteries (coronary arteriospasm)

** if Xenetix concentration in cerebral arterial blood is high*

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE XENETIX

Keep this medicine out of the reach and sight of children.

Vial: Keep the container in the outer carton. Do not store above 30°C
Bags: Keep the container in the outer carton

Do not use Xenetix after the expiry date which is stated on the vial or the bag and on the carton, after the abbreviation "Exp". The expiry date refers to the last day of that month.

Do not use Xenetix if you notice visible signs of deterioration of the product

- It is unlikely that you will be asked to dispose of any left over Xenetix. If this happens ask your pharmacist what you should do. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Xenetix contains

- The active substance is iobitridol. 100 millilitres (mLs) of solution for injection of:
  Xenetix 250 contains 54.84 g of iobitridol, corresponding to a quantity of 25 g of iodine.
  Xenetix 300 contains 65.81 g of iobitridol, corresponding to a quantity of 30 g of iodine.
  Xenetix 350 contains 76.78 g of iobitridol, corresponding to a quantity of 35 g of iodine.
- The other ingredients are: Sodium calcium edetate, trometamol, trometamol hydrochloride, water for injection, sodium hydroxide or hydrochloric acid (for pH adjustment)

What Xenetix looks like and contents of the pack

Xenetix is a clear, colourless or slightly yellow solution for injection
The solution for injection of Xenetix 250 is presented in the following containers sizes: 50 mL filled in 60 mL vial, 100 mL filled in 100 or 125 mL vial, 200 mL filled in 250 mL vial and 500 mL filled in 500 mL vial
The solution for injection of Xenetix 300 and Xenetix 350 is presented in the following containers sizes: 20 mL filled in 20 or 30 mL vial, 50 mL filled in 60 mL vial, 60 mL filled in 60 mL vial, 75 mL filled in 100 or 125 mL vial, 100 mL filled in 100 or 125 mL vial, 150 mL filled in 250 mL vial, 200 mL filled in 250 mL vial and 500 mL filled in 500 mL vial, and in 100 mL, 150 mL, 200 mL or 500 mL bags.

Not all pack sizes may be marketed.

Marketing Authorisation Holder/Manufacturer:

Guerbet
BP 57400 - 95943 Roissy CdG cedex - France

This leaflet was last revised in April 2015.

220588

Guerbet

Note: The PL mockup is available in 3 dimensions: 420 x 200 mm for large vial presentations (> or = to 75mL) , 455 x 140mm for smaller vial presentations (< or = to 60 mL), and 420 x 140mm for softbag presentations

Package leaflet: Information for the user

XENETIX 250 (250 mg I/mL), solution for injection
XENETIX 300 (300 mg I/mL), solution for injection
XENETIX 350 (350 mg I/mL), solution for injection

Iobitridol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effect, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

1. WHAT XENETIX IS AND WHAT IT IS USED FOR

Xenetix is a diagnostic agent. It belongs to the group of contrast agents used for radiological examinations.

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This medicine is for diagnostic use only.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE XENETIX

You should read the information in this section carefully.
You and your doctor should consider this information before you are given Xenetix.

Do not use Xenetix if:
- you are allergic to iobitridol or any of the other ingredients of Xenetix (listed in section 6)
- you have already had an allergic reaction following the injection of iobitridol (see section 4: possible side effects)
- you have excess thyroid hormones (these are hormones that affect your energy level)
- you are pregnant or think you are pregnant and are due to undergo hysterosalpingography (examination of the uterus and fallopian tubes)

Warnings and precautions
Inform your doctor if the following applies to you:
- you have previously had an allergic reaction to a contrast agent during an examination
- you are asthmatic and have had an asthma attack within the 8 days preceeding the examination
- you have a history of allergic reaction to anything
- you have sickle cell disease (an inherited blood disorder that affects red blood cells)
- you have any condition that could cause a water or electrolyte imbalance (for example dehydration, increase of sodium in your blood, which may change the amount of certain body salts, eg calcium, potassium, sodium… in your body)
- you are being treated with a beta-blocker (medicine for heart and blood pressure disorders)
- you have kidney problems
- you have liver disease
- you have pancreatitis
- you have a disease affecting your heart or your blood vessels
- you have had convulsions or you are being treated for epilepsy
- you have heart failure (your heart is not pumping well)
- you have diabetes
- you have had a stroke or recent history of intracranial haemorrhage (bleeding inside the skull)
- you have myasthenia gravis
- you have thyroid disorders or a history of thyroid disease
- you have a phaeochromocytoma (tumour of the adrenal gland)
- you have bone-marrow disease (monoclonal gammapathy: multiple myeloma or Waldenström's disease)
- you are due to undergo a thyroid examination in the near future or treatment with radioactive iodine
- you regularly drink large amounts of alcohol or you use drugs
- you have anxiety, nervousness or pain, as possible side-effects may be intensified.
- you have or have ever had inflammation in the pelvis affecting your womb, tubes or ovaries.

In all these cases, your doctor will only give you Xenetix if the benefits outweigh the risks. If you are given Xenetix, your doctor will take the precautions necessary and the administration of Xenetix will be carefully monitored.

Other medicines and Xenetix
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
In particular, please inform your doctor or pharmacist if:
- you are taking or have recently taken medicines for:
  - heart and blood pressure disorders such as beta-blockers or diuretics
  - diabetes (metformin)
- you have recently received interleukin-2 (a drug for treating cancer)

Xenetix with food and drink
There are no known interactions between Xenetix and food and drinks. However, please check with your doctor or pharmacist if it is required not to eat or drink before the examination.
You should inform your doctor if you regularly drink large quantities of alcohol (see section 2-Warnings and precautions).

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Xenetix may pass into your breast milk.

Driving and using machines
Xenetix is unlikely to affect your ability to drive or use machines. If you feel unwell after the examination, you should not drive or use machines.

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

3. HOW TO USE XENETIX

Xenetix will be administered to you by injection.

During the examination, you will be under the supervision of a doctor. A plastic needle will be left in your vein; this will allow the doctor to inject you with appropriate emergency drugs if necessary. If you experience an allergic reaction, the administration of Xenetix will be stopped.

The procedure will be carried out in a hospital, clinic or private practice. The attending staff know what precautions have to be taken for the examination. They are also aware of any possible complications that can occur.

Dosage
Your doctor will determine the dose you will receive and supervise the injection.

If too much Xenetix has been administered to you
It is highly unlikely that you will be given an overdose. You will be given Xenetix in a medical setting by a trained person. In a real case of overdose, Xenetix can be removed from the body by haemodialysis (blood cleaning).

Speak to your doctor if you are unsure or worried.

If you have any further questions on the use of this product ask your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Xenetix can cause side effects, although not everybody gets them.

Most side effects occur during the injection or within the first hour following administration. Some effects can occur up to several days after Xenetix injection.

Side effects of Xenetix are generally mild to moderate and are temporary.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please also tell your doctor or pharmacist as soon as possible.

There is a small risk (rare) that you may have an allergic reaction to Xenetix. Such reactions can be severe and **exceptionally result in shock** (very rare case of allergic reaction that could put your life in danger).

Any of the symptoms listed below may be the first signs of shock. Immediately inform your doctor or health professional if you have any of them.

- swelling of the face, mouth or throat which may cause you difficulties in swallowing or breathing
- hypotension (low blood pressure)
- breathing difficulties
- wheezy breathing
- coughing
- itching
- runny nose
- sneezing
- skin rash
- urticaria (patches of red skin, severe itching)
- Stevens-Johnson syndrome or Lyell's syndrome (severe allergic skin reaction with blister like lesions)

Altogether, the side effects which have been described for Xenetix are the following:

Uncommon side effects (probably affecting fewer than 1 in 100 people)
- sensation of warmth
- nausea

Rare side effects (probably affecting fewer than 1 in 1,000 people)
- swelling of various parts of the body including the face
- tightness sensation in the throat
- hypotension (low blood pressure)
- breathing difficulties
- wheezy breathing
- coughing
- sneezing
- eye irritation
- vertigo (feeling of spinning or dizziness)
- malaise (feeling of discomfort or being unwell)
- vomiting
- tachycardia (fast heart rate)
- urticaria (patches of red skin, severe itching)
- other skin reaction
- injection site pain
- chill
- tremor
- presyncope (lightheaded)
- paresthesia (feeling of pins and needles in a limb)

Very rare side effects (probably affecting fewer than 1 in 10,000 people)
- thyroid disorder
- coma*
- convulsions (fits)*
- confusion*
- visual disorders*
- memory loss*
- photophobia (fear of light)*
- transient blindness*
- drowsiness*
- agitation*
- headache
- hearing difficulties
- cardiac arrest
- blood creatinine increased
- changes to heart rate, angina or heart attack (heavy chest pain radiating up left arm)
- circulatory failure
- myocardial infarction
- abdominal pain
- kidney disorders
- breathing difficulties caused by tightening of the muscles in your airways or water in the lungs
- swelling of throat
- eczema
- severe allergic skin reaction including reaction with blister like lesions

If Xenetix is accidentaly injected outside the vein, pain can occur around the site of injection with swelling, inflammation, local reddening or necrosis.

Other side effect (frequency undertermined on the basis of the available data):
- joint pain (when Xenetix is administered into joints)
- pelvic pain (when Xenetix is administered into the uterus and fallopian tubes)
- high blood pressure (hypertension)
- abnormal heartbeats may occur (torsades de pointes)
- temporary discomfort or pain that is caused by a temporary spasm (constriction) in one or more of your coronary arteries (coronary arteriospasm)

** if Xenetix concentration in cerebral arterial blood is high*

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE XENETIX

Keep this medicine out of the reach and sight of children.

Vial: Keep the container in the outer carton. Do not store above 30°C
Bags: Keep the container in the outer carton

Do not use Xenetix after the expiry date which is stated on the vial or the bag and on the carton, after the abbreviation "Exp". The expiry date refers to the last day of that month.
Do not use Xenetix if you notice visible signs of deterioration of the product.

- It is unlikely that you will be asked to dispose of any left over Xenetix. If this happens ask your pharmacist what you should do. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Xenetix contains

- The active substance is iobitridol. 100 millilitres (mLs) of solution for injection of:
  Xenetix 250 contains 54.84 g of iobitridol, corresponding to a quantity of 25 g of iodine.
  Xenetix 300 contains 65.81 g of iobitridol, corresponding to a quantity of 30 g of iodine.
  Xenetix 350 contains 76.78 g of iobitridol, corresponding to a quantity of 35 g of iodine.
- The other ingredients are: Sodium calcium edetate, trometamol, trometamol hydrochloride, water for injection, sodium hydroxide or hydrochloric acid (for pH adjustment)

What Xenetix looks like and contents of the pack

Xenetix is a clear, colourless or slightly yellow solution for injection
The solution for injection of Xenetix 250 is presented in the following containers sizes: 50 mL filled in 60 mL vial, 100 mL filled in 100 or 125 mL vial, 200 mL filled in 250 mL vial and 500 mL filled in 500 mL vial
The solution for injection of Xenetix 300 and Xenetix 350 is presented in the following containers sizes: 20 mL filled in 20 or 30 mL vial, 50 mL filled in 60 mL vial, 60 mL filled in 60 mL vial, 75 mL filled in 100 or 125 mL vial, 100 mL filled in 100 or 125 mL vial, 150 mL filled in 250 mL vial, 200 mL filled in 250 mL vial and 500 mL filled in 500 mL vial, and in 100 mL, 150 mL, 200 mL or 500 mL bags.

Not all pack sizes may be marketed.

Marketing Authorisation Holder/Manufacturer:

Guerbet
BP 57400
95943 Roissy CdG cedex
France

This leaflet was last revised in April 2015.

220589

Guerbet

Note: The PL mockup is available in 3 dimensions: 420 x 200 mm for large vial presentations (> or = to 75mL) , 455 x 140mm for smaller vial presentations (< or = to 60 mL), and 420 x 140mm for softbag presentations.

Package leaflet: Information for the user

XENETIX 250 (250 mg I/mL), solution for injection
XENETIX 300 (300 mg I/mL), solution for injection
XENETIX 350 (350 mg I/mL), solution for injection

Iobitridol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
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You and your doctor should consider this information before you are given Xenetix.

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Warnings and precautions
Inform your doctor if the following applies to you:
- you have previously had an allergic reaction to a contrast agent during an examination
- you are asthmatic and have had an asthma attack within the 8 days preceeding the examination
- you have a history of allergic reaction to anything
- you have sickle cell disease (an inherited blood disorder that affects red blood cells)
- you have any condition that could cause a water or electrolyte imbalance (for example dehydration, increase of sodium in your blood, which may change the amount of certain body salts, eg calcium, potassium, sodium… in your body)
- you are being treated with a beta-blocker (medicine for heart and blood pressure disorders)
- you have kidney problems
- you have liver disease
- you have pancreatitis
- you have a disease affecting your heart or your blood vessels
- you have had convulsions or you are being treated for epilepsy
- you have heart failure (your heart is not pumping well)
- you have diabetes
- you have had a stroke or recent history of intracranial haemorrhage (bleeding inside the skull)
- you have myasthenia gravis
- you have thyroid disorders or a history of thyroid disease
- you have a phaeochromocytoma (tumour of the adrenal gland)
- you have bone-marrow disease (monoclonal gammapathy: multiple myeloma or Waldenström's disease)
- you are due to undergo a thyroid examination in the near future or treatment with radioactive iodine
- you regularly drink large amounts of alcohol or you use drugs
- you have anxiety, nervousness or pain, as possible side-effects may be intensified.
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In particular, please inform your doctor or pharmacist if:
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  - diabetes (metformin)
- you have recently received interleukin-2 (a drug for treating cancer)

Xenetix with food and drink
There are no known interactions between Xenetix and food and drinks. However, please check with your doctor or pharmacist if it is required not to eat or drink before the examination.
You should inform your doctor if you regularly drink large quantities of alcohol (see section 2-Warnings and precautions).

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If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Xenetix may pass into your breast milk.

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Your doctor will determine the dose you will receive and supervise the injection.

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- hypotension (low blood pressure)
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- runny nose
- sneezing
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- sneezing
- eye irritation
- vertigo (feeling of spinning or dizziness)
- malaise (feeling of discomfort or being unwell)
- vomiting
- tachycardia (fast heart rate)
- urticaria (patches of red skin, severe itching)
- other skin reaction
- injection site pain
- chill
- tremor
- presyncope (lightheaded)
- paresthesia (feeling of pins and needles in a limb)

Very rare side effects (probably affecting fewer than 1 in 10,000 people)
- thyroid disorder
- coma*
- convulsions (fits)*
- confusion*
- visual disorders*
- memory loss*
- photophobia (fear of light)*
- transient blindness*
- drowsiness*
- agitation*
- headache
- hearing difficulties
- cardiac arrest
- blood creatinine increased
- changes to heart rate, angina or heart attack (heavy chest pain radiating up left arm)
- circulatory failure
- myocardial infarction
- abdominal pain
- kidney disorders
- breathing difficulties caused by tightening of the muscles in your airways or water in the lungs
- swelling of throat
- eczema
- severe allergic skin reaction including reaction with blister like lesions

If Xenetix is accidentaly injected outside the vein, pain can occur around the site of injection with swelling, inflammation, local reddening or necrosis.

Other side effect (frequency undertermined on the basis of the available data):
- joint pain (when Xenetix is administered into joints)
- pelvic pain (when Xenetix is administered into the uterus and fallopian tubes)
- high blood pressure (hypertension)
- abnormal heartbeats may occur (torsades de pointes)
- temporary discomfort or pain that is caused by a temporary spasm (constriction) in one or more of your coronary arteries (coronary arteriospasm)

** if Xenetix concentration in cerebral arterial blood is high*

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE XENETIX

Keep this medicine out of the reach and sight of children.

Vial: Keep the container in the outer carton. Do not store above 30°C
Bags: Keep the container in the outer carton

Do not use Xenetix after the expiry date which is stated on the vial or the bag andon the carton, after the abbreviation "Exp". The expiry date refers to the last day of that month.

Do not use Xenetix if you notice visible signs of deterioration of the product.
- It is unlikely that you will be asked to dispose of any left over Xenetix. If this happens ask your pharmacist what you should do. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Xenetix contains

- The active substance is iobitridol. 100 millilitres (mLs) of solution for injection of:
  Xenetix 250 contains 54.84 g of iobitridol, corresponding to a quantity of 25 g of iodine.
  Xenetix 300 contains 65.81 g of iobitridol, corresponding to a quantity of 30 g of iodine.
  Xenetix 350 contains 76.78 g of iobitridol, corresponding to a quantity of 35 g of iodine.
- The other ingredients are: Sodium calcium edetate, trometamol, trometamol hydrochloride, water for injection, sodium hydroxide or hydrochloric acid (for pH adjustment)

What Xenetix looks like and contents of the pack

Xenetix is a clear, colourless or slightly yellow solution for injection
The solution for injection of Xenetix 250 is presented in the following containers sizes: 50 mL filled in 60 mL vial, 100 mL filled in 100 or 125 mL vial, 200 mL filled in 250 mL vial and 500 mL filled in 500 mL vial
The solution for injection of Xenetix 300 and Xenetix 350 is presented in the following containers sizes: 20 mL filled in 20 or 30 mL vial, 50 mL filled in 60 mL vial, 60 mL filled in 60 mL vial, 75 mL filled in 100 or 125 mL vial, 100 mL filled in 100 or 125 mL vial, 150 mL filled in 250 mL vial, 200 mL filled in 250 mL vial and 500 mL filled in 500 mL vial, and in 100 mL, 150 mL, 200 mL or 500 mL bags.

Not all pack sizes may be marketed.

Marketing Authorisation Holder/Manufacturer:

Guerbet
BP 57400
95943 Roissy CdG cedex
France

This leaflet was last revised in April 2015.

220342

Guerbet