PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Xenetix 250 (250 mgI/mL), solution for injection
Xenetix 300 (300 mgI/mL), solution for injection
Xenetix 350 (350 mgI/mL), solution for injection

lobitridol

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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

1. What Xenetix is and what it is used for
2. What you need to know before you use Xenetix
3. How to use Xenetix
4. Possible side effects
5. How to store Xenetix
6. Contents of the pack and other information

1. WHAT XENETIX IS AND WHAT IT IS USED FOR

Xenetix belongs to the class of iodinated contrast agents. These medicinal products are used during radiological examinations. Xenetix enhances the contrast of images obtained during these examinations, which improves the visualisation and delineation of the contours of certain parts of the body.
This medicinal product is for diagnostic use only.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE XENETIX

Do not use Xenetix
- if you have previously developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Xenetix.
- if you are allergic to the active substance (iobitridol) or any of the other ingredients in Xenetix. See the list of ingredients in Section 6. 'Further information'.
- if you have had an allergic reaction to a medicinal product containing the same active substance (iobitridol) (also see Section 4. 'Possible side effects').
- if you have excessive levels of thyroid hormones (thyrotoxicosis).
- if you are pregnant, or if you think you are pregnant, and if you are scheduled for an examination of the uterus and uterine tubes (hysterosalpingography).

Warning and Precautions
Talk to your doctor or pharmacist before using Xenetix.

As with all iodinated contrast agents, whatever the administration route and dose, side effects are possible, which may be mild but can also be life-threatening. These effects can occur within one hour after administration or, more rarely, as much as seven days later. They are often unpredictable, but the risk is higher if you have experienced a reaction during previous administration of an iodinated contrast agent (see Section 4, 'Possible side effects').

Before the examination, you should inform your doctor if you are in any of the following situations:
- You have previously reacted to an iodinated contrast agent during an examination
- You have previously developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Xenetix or other iodinated contrast media.
- You have poor kidney function (renal failure).
- You have both poor kidney function (renal failure) and poor liver function (hepatic failure).
- You are dehydrated.
- You have heart problems (heart failure) or any other disease of the heart or blood vessels.
- You have high levels of blood sugar (diabetes).
- You have pancreatic disease (acute pancreatitis).
- You are asthmatic and have had an asthma attack within eight days prior to the examination.
- You have had convulsions or have epilepsy.
- You have had a stroke, or you have experienced bleeding in your head (intracranial bleeding).
- You have an increased amount of liquid in your brain (cerebral oedema).
- You have excessive hormone production causing severe high blood pressure (phaeochromocytoma).
- You have a muscular disease (myasthenia).
- You have or have had thyroid disease.
- You are scheduled for a thyroid examination or treatment with radioactive iodine.
- You have bone marrow disease (myeloma, monoclonal gammopathy: multiple myeloma or Waldenstrom's macroglobulinaemia).
- You have excess uric acid in the blood, e.g. in case of gout.
- You experience anxiety, nervousness or you have pains (the side effects can be increased).
- You regularly drink large quantities of alcohol or you use drugs.
- You have any other disease.

Take special care with Xenetix

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (Lyell's syndrome or TEN) and acute exanthematous pustulosis (AGEP), which can be life-threatening, have been reported with the use of Xenetix.

If you develop a serious rash or another of these skin symptoms, contact your doctor or seek medical attention immediately.

During or shortly after the imaging procedure you may experience a short-term brain disorder called encephalopathy. Seek medical attention immediately if you notice any of the symptoms related to this condition described in section 4.

Children

Thyroid disorders may be observed after administration of Xenetix. Special care should be taken in newborns, including those whose mother received Xenetix during pregnancy, and premature infants and younger children. Doctors may check the child's thyroid gland function.

Other medicines and Xenetix
Tell your doctor or pharmacist if you are taking or have recently taken:
- a medicine to treat high blood sugar levels (metformin),
- a medicine to treat heart disease or high blood pressure (a beta blocker or diuretic),
- a medicine used particularly to treat certain cancers (interleukin-2).

If you are taking or have recently taken or might take any other medicines, including those that do not require a medical prescription, inform your doctor or pharmacist.

Xenetix with food, drink and alcohol
Ask your doctor or pharmacist to know if you need to not eat or drink before the examination.
You should inform your doctor if you regularly drink large quantities of alcohol (see Section2 – Warnings and precautions).

Pregnancy, breast-feeding and fertility
Pregnancy
You should never take Xenetix if you are pregnant or think you may be pregnant and if you are scheduled for an examination of the uterus and uterine tubes (connecting the uterus to the ovaries).
For other examinations, if you are pregnant, or if your period is late, you must inform the doctor before the radiological examination.
Ask your doctor or pharmacist for advice before taking any medicine.

If this medicine has been given to a woman during pregnancy, or to a newborn baby, doctors should check the baby's thyroid gland function, as these babies may temporarily have an underactive thyroid gland (hypothyroidism).

Breastfeeding
Xenetix may be secreted in breast milk.
You should not breastfeed for at least 24 hours after administration of Xenetix.
Ask your doctor or pharmacist for advice before taking any medicine

Driving and using machines
No particular risks are known.
If you do not feel well 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 mLi.e. is essentially "sodium-free".

3. HOW TO USE XENETIX

Posology
Your doctor will determine the dose he/she has to inject. The dose will depend on several factors, including the type of examination you are undergoing.

Method and route of administration
Your doctor will inject this product into a blood vessel (intravascular route) or into a body cavity (intra-articular or intra-uterine route) before performing the examination.

If you take more Xenetix than you should
It is highly unlikely that you will receive an excessive dose of Xenetix as it will be administered to you in a medical setting by a qualified person. In the event of overdose, Xenetix can be eliminated by haemodialysis (procedure to clean the blood).
If you have any questions or doubts, ask your doctor or pharmacist for more information.

Additional information regarding the use and handling by the medical or healthcare professional is given at the end of this leaflet.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Xenetix can cause side effects, but not everyone experiences them.

There is a small risk (rare) that you may have an allergic reaction to Xenetix. Such reactions can be severe and **may exceptionally result in shock** (very rare case of allergic reaction that could put your life in danger). **An allergy can be recognised by the following effects:**
- reactions that appear very rapidly (often within an hour) with pimples on the skin, redness (erythema) and itching (localised or extensive hives), sudden swelling of the face and neck (angioneurotic edema)
- reactions that appear later on the skin, i.e. red pimples (macular or papular eruptions) and in exceptional cases, serious extensive skin lesions with the appearance of blisters on the body (Lyell's or Stevens-Johnson syndrome) red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis) or widespread rash, high

body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (drug reaction with eosinophilia and systemic symptoms which is also known as DRESS or drug hypersensitivity syndrome). See also section 2.

- respiratory effects: cough, nasal inflammation (rhinitis), tightness in the throat, breathing difficulties, swollen throat (laryngeal oedema), breathing difficulties combined with coughing (bronchial spasm), respiratory collapse
- effects on the heart and blood vessels: low blood pressure (hypotension), vertigo, dizziness, malaise, heart rhythm disorders, Blue skin coloration due to low oxygen in the blood *(*cyanosis), cardiac arrest
- gastrointestinal effects: nausea, vomiting, abdominal pains

If you experience any of these effects during or after injection of Xenetix, you should immediately inform your doctor.

Overall the following side effects have been described for Xenetix

Uncommon side effects (affecting 1 to 10 out of every 1,000 patients treated):

- Sensation of warmth
- Nausea

Rare side effects (affecting 1 to 10 out of every 10,000 patients treated):

- Weakness (dizziness and feeling you might be about to lose consciousness), trembling, strange sensations such as tingling
- Dizziness
- Effects on the heart and blood vessels, including increased or decreased heart rate
- Low blood pressure
- High blood pressure
- Breathing difficulties, cough, sensation of constriction in the throat, sneezing
- Vomiting
- Swelling of the skin and mucous membranes, particularly in the face, nettle rash (very itchy red spots on your skin), other skin reactions, itching
- Malaise, chills, pain at the injection site

Very rare side effects (affecting fewer than 1 in 10,000 patients treated):

- Thyroid dysfunction
- Coma*, convulsions*, confusion*, visual disturbances*, memory loss*, aversion to light*, temporary blindness*, drowsiness*, restlessness*, feeling agitated*, headache
- Hearing impairment
- Cardiac arrest, heart attack, heart rhythm disturbances, angina attacks (severe chest pain radiating to the left arm)
- Heart and blood vessels fail to work properly
- Respiratory arrest, breathing difficulties caused by bronchial spasms or water on the lungs such as wheezing, swelling of the throat, sensation of constriction in the throat
- Abdominal pain
- Severe allergic skin reactions with blistering and redness of the skin, eczema
- Kidney failure, severely reduced urinary output
- Pain at the injection site with swelling, inflammation, local redness and tissue damage if Xenetix is accidentally introduced outside the blood vessels
- Elevated blood creatinine values
- Severe heart rhythm disorder (torsades de pointes), temporary discomfort or pain caused by a temporary spasm (narrowing) of one or more of the coronary arteries of your heart

** These occurred when high Xenetix concentrations were used in examinations of the arterial circulation in the brain.*

The frequency of the following undesirable effects is not known: (frequency cannot be estimated from the available data):

- Transient neonatal hypothyroidism, hypothyroidism*

- Dizziness in a context of hypersensitivity reaction,
- Blue skin coloration due to low oxygen in the blood (cyanosis) in a context of hypersensitivity reaction
- Short term brain disorders (encephalopathy) which can cause headache, confusion, difficulties with vision, loss of vision, seizures, loss of coordination, weakness on one side of the body, problems with speech and loss of consciousness.
- An allergic skin reaction that may include round or oval patches of redness and swelling of the skin, blistering, and itching (fixed drug eruption). Darkening of the skin in affected areas, which might persist after healing, may also occur.
  Fixed drug eruption usually reoccurs at the same site(s) if the medication is used again.

Additional side effects in children

* Short-term underactive thyroid gland (transient hypothyroidism) has been reported in young children after exposure to similar iodinated contrast agents.

If you experience any side effects not mentioned in this leaflet, or if you experience effects that are described here as serious, inform your doctor or pharmacist.

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 the national reporting system HPRA Pharmacovigilance Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE XENETIX

Keep out of the reach and sight of children.
Bottles : keep container in the outer carton in order to protect from light. Do not store above 30°C.
Bags: keep the container in the outer carton in order to protect from light. Do not remove from overwrap until immediately before use.

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

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

What Xenetix contains

Xenetix is a clear, colourless or slightly yellow solution for injection. The
active substance is iobitridol. 1 millilitre of solution for injection of :
Xenetix 250 contains 548.4 mg of iobitridol, corresponding to a quantity of 250 mg of iodine.
Xenetix 300 contains 658.1 mg of iobitridol, corresponding to a quantity of 300 mg of iodine.
Xenetix 350 contains 767.8 mg of iobitridol, corresponding to a quantity of 350 mg of iodine.

The other ingredients are: sodium calcium edetate, trometamol, trometamol hydrochloride, water for injection, sodium hydroxide or hydrochloric acid (for pH adjustment).

Packaging

The solution for injection of Xenetix 250 is in 50 mL, 100 mL, 200 mL and 500 mL vial.

The solution for injection of Xenetix 300 is in 20 mL, 50 mL, 60 mL, 75 mL, 100 mL, 150 mL, 200 mL and 500 mL vials and 100 mL, 150 mL, 200 mL, 500 mL polypropylene bags
The solution for injection of Xenetix 350 is in 20 mL, 50 mL, 60 mL, 75 mL, 100 mL, 150 mL, 200 mL and 500 mL vials and 100 mL, 150 mL, 200 mL, 500 mL polypropylene bags

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<To be completed nationally>

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INFORMATION FOR THE HEALTHCARE PROFESSIONAL

The following information is intended for medical or healthcare professionals only. For full prescribing information please consult the Summary of Product Characteristics.

Dosage and method of administration

Adults and Children:
The doses should be adapted to the type of examination and the regions to be opacified as well as the weight and renal function of the patient, especially in children.

Mean dose recommended for all indications:

Indications for Xenetix 250	**Recommended dosage**	
Whole-body CT	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.	
Venography	mean dose: 2.6 mL/kg	min/max dose: 50-100 mL per leg (maximum usual total dose: 250 mL)
Intra-arterial digital subtraction angiography	mean dose: 3.1 mL/kg	min/max dose: 1.0-5.5 mL/kg

Indications for Xenetix 300	*Recommended dosage*	
Urography	Adults	Minimum dose: 1 mL/kg. It may be necessary to increase the dose in individual cases e.g. obesity or impaired renal function.
	Children	The poor concentrating ability of immature nephron of infantile kidneys necessitates the use of relatively high doses of contrast medium, i.e.: Neonates: 4.0 mL/kg Babies: 3.0 mL/kg Small children: 1.5 mL/kg
Brain CT	Adults	1-2 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	0.9-2.3 mL/kg	
Intravenous digital subtraction angiography	Mean dose: 1.7 mL/kg		Min/max dose: 0.6-3.6 mL/kg
Arch aortography	30-40 mL/inj.		
Selective cerebral arteriography	5-10 mL/inj.		
Aortography	40-50 mL/inj.		
Femoral arteriography	30-50 mL/inj.		
various	Depending on type of examination		
Angiocardiography	Mean dose: 1.1 mL/kg		Min/max dose: 0.9-1.4 mL/kg
Arthrography	5-20 mL, according to joint being examined		
Hysterosalpingography	5-20 mL, to adapt to the uterine volume		

Indications for Xenetix 350	**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.	

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.