Package leaflet: Information for the user

Optiray 320 mg I/ml,
solution for injection or infusion, multidose container

Active substance: Ioversol

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.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Optiray is and what it is used for
Optiray is used in adults for several types of X-ray procedures including:
- **imaging of vessels**, both arteries and veins
- **kidneys**
- **CT scans**

Optiray is an X-ray contrast medium containing iodine. The iodine blocks the X-rays, allowing vessels and the inner organs supplied with blood to be seen.

2. What you need to know before you use Optiray
Do not use Optiray
- if you are **allergic** to **contrast media** substances containing iodine or to any of the other ingredients of this medicine (listed in section 6)
- if you have an **overactive thyroid gland**

Warnings and precautions
Talk to your doctor before using Optiray if you have
- or previously had allergic reactions such as nausea, vomiting, low blood pressure, skin symptoms
- asthma
- heart failure, high blood pressure, circulation disorders, or had a stroke, and if you are very elderly
- diabetes
- kidney or liver disease
- brain disorders
- problems with bone marrow, such as certain blood cancers known as multiple myeloma, Waldenström's macroglobulinaemia
- certain red blood cell abnormalities, known as sickle cell anaemia
- a tumour of the adrenal gland, which affects your blood pressure, known as phaeochromocytoma
- increased homocysteine amino acid level, due to abnormal metabolism

- recent gall bladder investigation with contrast media
- a planned thyroid gland investigation using a substance containing iodine
  This should be postponed as Optiray may influence results for up to 16 days.

Signs of an allergic reaction to this medicine, including breathing problems and chest pain, have been reported with Optiray. Tell your doctor immediately if you notice any of these signs.

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 Optiray.

During or shortly after the imaging procedure you may experience a short-term brain disorder called encephalopathy. Tell your doctor straight away if you notice any of the symptoms related to this condition described in section 4.

Children younger than 18 years
Optiray 320 is not recommended in this age group. In case of exposure (direct exposure or newborns whose mothers have received a iodinated contrast medium during pregnancy), thyroid function should be evaluated at birth and in all pediatric patients younger than 3 years, within one month following exposure.

Other medicines and Optiray
Tell your doctor or X-ray specialist if you are using, have recently used or might use any other medicines.

The following **medicines** can **influence or be influenced by Optiray**
- **metformin:** a medicine to treat diabetes
  Your doctor will measure your kidney function before and after Optiray use. Metformin should be stopped before the investigation. It should not be re-started for at least 48 hours after the investigation and only when your kidney function has returned to its previous level.
- **interleukin:** medicines to treat certain tumours
- **certain medicines to increase blood pressure** due to narrowing of blood vessels
  To prevent any risk of nervous disorders, Optiray should never be used while using these medicines.
- **general anaesthetics**
  A higher frequency of side effects has been reported.
- **diuretics:** medicines that increase urine production and lower blood pressure
  In case of dehydration caused by the use of diuretics, the use of iodinated contrast media may increase the risk of acute kidney failure.

Pregnancy and breast-feeding
- **Pregnancy**
  Tell your doctor if you are pregnant or think you could be. Your doctor will only administer Optiray during pregnancy if it is absolutely necessary, as it could harm the unborn child.

- **Breast-feeding**
  Discontinue breast-feeding for one day after the injection, as insufficient information exists concerning safety. Discuss this with your doctor or X-ray specialist.

Driving and using machines
Driving or operating machines **is not advisable for up to 1 hour after** injection.
In addition, symptoms such as dizziness, drowsiness, fatigue and visual disturbances have been reported. If this affects you, do not attempt any activities which require concentration and the ability to react appropriately.

Optiray contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per 100 ml, that is to say essentially "sodium-free".

3. How to use Optiray

Optiray investigations will **only** be performed **by a doctor or X-ray specialist**, who will also decide the dose.
Optiray is **injected into a blood vessel** and distributed throughout the body by the blood stream. It will be warmed to body temperature before use, then injected once or more during the X-ray procedure.
The dose depends on the specific procedure you are having and other factors such as your health and age.
The lowest dose possible will be used to produce adequate X-ray images.

If more Optiray is given than it should
Overdoses are potentially dangerous and may affect the breathing, heart and circulation system. Inform your doctor or X-ray specialist immediately if you notice any of these symptoms after receiving Optiray.

If you have any further questions on the use of this medicine, ask your doctor or X-ray specialist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Side effects associated with Optiray are generally independent of the dose given. In the majority of cases they are mild or moderate and very rarely serious or life-threatening.

Contact a doctor immediately if you develop any of the following **signs of serious side effects:**
- heart or breathing arrest
- heart vessel spasms or blood clots
- stroke, blue lips, fainting
- loss of memory
- speech disorders
- sudden movements
- temporary blindness
- acute kidney failure
- skin rash, redness or blisters, which may develop into life-threatening skin reactions including extensive peeling of the skin (toxic epidermal necrolysis), or a drug reaction that causes rash, fever, inflammation of internal organs, hematologic abnormalities and systemic illness (DRESS)
- signs of allergic reactions, such as
  - allergic shock
  - tightened airways
  - swelling of the voice box, throat, tongue
  - breathing difficulties
  - cough, sneezing
  - reddening and/or swelling of the face and eyes
  - itching, rash and hives

Side effects can occur with the following frequencies:
very common, occurs in more than 1 of 10 users
- feeling hot

common, occurs in 1 to 10 per 100 users
- pain

- nausea

uncommon, occurs in 1 to 10 per 1,000 users
- hives
- skin redness, itching,
- dizziness
- headache
- taste disturbance
- abnormal sensation, such as pricking, tingling
- vomiting
- sneezing
- high blood pressure

rare, occurs in 1 to 10 per 10,000 users
- fainting
- vertigo
- blurred vision
- racing pulse
- low blood pressure
- flushing
- larynx spasms
- swelling and narrowing of airways, including throat tightness, wheezing
- difficult breathing
- inflammation inside the nose which causes sneezing and blocked nose
- cough, throat irritation
- dry mouth
- rash
- urgent urination
- swelling of the face including eyes
- chills
- uncontrollable shaking
- feeling cold

very rare, occurs in fewer than 1 per 10,000 users
- severe allergic reaction
- confusion, anxiety, restlessness
- loss of consciousness, numbness
- paralysis
- drowsiness
- stupor
- speech disorders
- language disorders
- reduced sense of touch or sensation
- allergic eye inflammation causing red, watery and itchy eyes
- ringing or buzzing in the ears
- irregular heartbeats, slow pulse
- chest pain
- heart activity changes measured using ECG
- disease which disturbs blood flow through the brain
- high blood pressure
- vein inflammation, blood vessel dilation
- fluid accumulation in the lung
- sore throat

- low oxygen in the blood
- abdominal pain
- salivary gland inflammation, swelling of the tongue
- difficulty in swallowing, increased salivation
- mostly painful severe swelling of deep skin layers, mainly in the face
- increased sweating
- muscle spasms
- acute kidney failure or abnormal kidney function
- urinary incontinence, blood in urine
- tissue swelling caused by excess fluid
- injection site reactions including pain, reddening, bleeding or degeneration of cells
- feeling unwell or abnormal, tiredness, sluggishness

not known: frequency cannot be estimated from the available data
- severe allergic shock reaction
- temporarily underactive thyroid
- fits
- short term brain disorders (encephalopathy) which can cause confusion, hallucination, visual disturbance, blindness, seizures loss of coordination, loss of movement in one side of the body, problems with speech and loss of consciousness.
- movement disorder
- loss of memory
- temporary blindness
- heart arrest, life-threatening irregular heartbeat
- extra heartbeat
- heart artery cramps, pounding of the heart
- blue skin colouration due to low oxygen in the blood
- shock
- blood clot or spasm in a blood vessel
- paleness
- breathing arrest, asthma, tightened airways
- reduced ability to produce voice sounds using the vocal organs
- diarrhoea
- severe reaction affecting the skin, blood and internal organs (drug reaction with eosinophilia and systemic symptoms also known as DRESS or drug hypersensitivity syndrome)
- red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (Acute Generalized Exanthematous Pustulosis)
- red pimples (macular or papular eruptions)
- life-threatening reaction with flu-like symptoms and painful rash / blistering affecting the skin, mouth, eyes and genitals (Steven-Johnson Syndrome / Toxic Epidermal Necrolysis)
- absent or painful/difficult urination
- underactive thyroid in newborns
- fever

Reporting of side effects
If you get any **side effects, talk to your doctor or X-ray specialist**. This includes any side effects not listed in this leaflet.
You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Optiray
Keep this medicine out of sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Keep the container in the outer carton in order to protect from light. Protect from X-rays. Do not store above 30°C. Optiray 320 can be stored for one month at 37°C in a contrast media warmer with circulating air.

Do not use this medicine if you notice discolouration or particulate matter.

6. Contents of the pack and other information

What Optiray contains

- The active substance is **Ioversol**.
  One millilitre of Optiray contains 678 mg Ioversol, which is equal to 320 mg of organically bound iodine.
- The other ingredients are sodium calcium edetate (stabiliser), trometamol and trometamol hydrochloride (buffer), and water for injections.
  Sodium hydroxide and hydrochloric acid may be used for adjustment pH of 6.0 to 7.4.

What Optiray looks like and contents of the pack

Optiray is packaged in uncoloured bottles. Bottles are fitted with 32 mm bromobutyl rubber closures and aluminium cap seals.
Pack sizes: 1x500 ml, 5x500 ml, 6x500 ml, 10x500 ml, respectively.

Not all pack sizes and box sizes may be marketed in all countries.

Marketing Authorisation Holder and Manufacturer

- **Marketing Authorisation Holder**
  <[To be completed nationally]>

  Manufacturer

  Guerbet, BP 57400, 95943 Roissy CdG Cedex, France located at 16-24 rue Jean Chaptal, 93600 Aulnay sous Bois, France

This leaflet was last revised in 05/2026

The following information is intended for medical or healthcare professionals only:

Special warnings and precautions for use

Serious or fatal reactions have been associated with the administration of iodinated X-ray contrast media. It is important to be prepared to treat any contrast medium reaction.

Such procedures, which involve the use of iodinated intravascular agents, should be performed under the direction of personnel skilled and experienced in the particular procedure to be performed. A fully equipped emergency cart, or equivalent supplies and equipment, and personnel competent in recognising and treating adverse reactions of all types should always be available. Since severe delayed reactions have been known to occur, the patient should be observed and emergency facilities and competent personnel should be available for at least 30 to 60 minutes after administration.

The anticoagulant effect of non-ionic X-ray contrast media has been shown, in vitro, to be less than that of conventional ionic agents at comparable concentrations. Similar results were found in some in

vivo studies. For this reason, meticulous angiographic techniques are recommended, e.g. frequent flushing of standard angiographic catheters and avoiding prolonged contact of blood with the contrast agent in syringes and catheters.

Optiray should be injected with caution to avoid perivascular application. Serious tissue damage (e.g. ulceration) has been reported in isolated cases requiring surgical treatment.

Incompatibilities
No other medicinal product should be mixed with Optiray.

Administration
Optiray 500 ml bottles must only be used with administration devices, e.g. infusion pumps or dual head injectors which are provided with reliable connecting tubes.
Optiray 500 ml bottles have a rubber stopper which can only be pierced once.
The manufacturer’s instructions for the device must be followed.

Shelf life
Any Optiray in 500 ml bottles which is unused at the end of the day must be discarded.