Package leaflet: Information for the user

Optiray® 350 mg I/ml PFS,
solution for injection

Active substance: Iodine (as 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. See section 4.

What is in this leaflet

1. What Optiray is and what it is used for
This medicine is for diagnostic use only. 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 an allergic reaction (symptoms of an allergic reaction can be difficulty breathing, collapse, swelling, nausea, vomiting, low blood pressure, skin symptoms)
- asthma
- heart failure
- diabetes
- kidney or liver disease
- brain disorders including problems with the mechanism that controls the passage of molecules from the blood into the brain
- problems with bone marrow, such as certain blood cancers known as paraproteinaemia, multiple myeloma
- 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.

Children younger than 18 years
Optiray 350 is not recommended in this age group.

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. Depending on the level of kidney function, your doctor may consider stopping metformin use between 48 hours before and at the time of 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.
- **general anaesthetics**
  A higher frequency of side effects has been reported.

Optiray with food and drink
Limit your food intake prior to the examination. Please, ask your doctor for advice. If you have kidney disease, do not limit your liquid intake as this may further reduce kidney function.

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**
  Your doctor or X-ray specialist may consider it necessary for you to stop breast-feeding for some time after the injection, as there is insufficient information concerning safety. You should discuss this with them.

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, tht 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.

Inform your doctor immediately if you develop any of the following **signs of serious side effects:**

- breathing/heart related difficulties
- chest pain/tightness
- leg swelling or pain, chest pain with shortness of breath
- weakness of a limb, facial weakness, problems with speech, blue lips, fainting
- loss of memory
- sudden movements
- temporary blindness
- kidney failure with rapid onset
- severe skin rash, sometimes with fever and blisters and/or swollen lymph nodes
- 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

uncommon, occurs in 1 to 10 per 1,000 users

- nausea
- hives

rare, occurs in 1 to 10 per 10,000 users

- fainting
- uncontrollable shaking
- dizziness, light-headedness
- headache
- abnormal sensation, such as pricking, tingling
- taste disturbance
- blurred vision
- racing pulse
- low blood pressure
- flushing
- spasm of the voice box
- swelling and narrowing of airways, including throat tightness, wheezing

- difficult breathing
- inflammation inside the nose which causes sneezing and blocked nose
- cough, throat irritation
- vomiting
- dry mouth
- skin redness, itching, rash
- urgent urination
- swelling of the face including eyes
- chills, 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
- problems with speech
- 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/tightness
- 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 cramps
- kidney failure with rapid onset or abnormal kidney function
- urinary incontinence, blood in urine
- tissue swelling caused by excess fluid
- injection site reactions including pain, reddening, bleeding or skin destruction
- feeling unwell or abnormal, tiredness, sluggishness

not known: frequency cannot be estimated from the available data
- severe allergic shock reaction
- temporarily underactive thyroid in newborns
- fits
- movement disorder
- loss of memory
- temporary blindness
- heart arrest, life-threatening irregular heartbeat
- extra heartbeat
- pounding of the heart
- blue skin colouration due to low oxygen in the blood
- shock
- leg swelling or pain, chest pain with shortness of breath, or spasm in a blood vessel

- breathing arrest, asthma, tightened airways
- reduced ability to produce voice sounds using the vocal organs
- diarrhoea
- mild to severe inflammatory skin rash, sometimes with fever and blisters and/or swollen lymph nodes
- paleness
- absent or painful/difficult urination
- fever

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:
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 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. Do not freeze. Optiray 350 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 350 PFS contains 741 mg Ioversol, which is equal to 350 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 350 PFS is an aqueous solution for injection. Optiray 350 PFS is packaged in prefilled hand-held syringes and power injector syringes made of polypropylene. Syringe tip cap and piston are made of natural rubber.

Prefilled hand-held syringes: 50 ml (box of 10)
Power injector syringes: 75 ml, 100 ml (boxes of 10 or 20)

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
- **Marketing Authorisation Holder**
  Guerbet, BP 57400, 95943 Roissy CdG Cedex, France

- **Manufacturer**
  Guerbet Ireland ULC, Damastown, Mulhuddart, Dublin 15, Ireland

Or

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

This leaflet was last revised in March 2021.

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

Healthcare professionals should consult the full prescribing information in the Summary of Product Characteristics.

Therapeutic indications
Optiray 350 PFS is a non-ionic X-ray contrast medium that is indicated in adults for use in coronary, peripheral, visceral, and renal arteriography, aortography and left ventriculography. Optiray 350 PFS is also indicated in adults for use in computed tomography (CT) of the head and body, intravenous urography, venography, and in intra-arterial and intravenous digital subtraction angiography (IA-DSA and IV-DSA).

Posology and method of administration
Adults
Recommended dosage schedule:

Procedure	Dosage *	Maximum Total Dose
Peripheral Arteriography	10-90 ml	250 ml
Venography	50-100 ml	250 ml
Left Ventriculography	30-50 ml	250 ml
Coronary Arteriography	1-10 ml	250 ml
Visceral Arteriography	12-60 ml	250 ml
Aortography	10-80 ml	250 ml
Renal Arteriography	6-15 ml	250 ml
Intravenous Urography	50-75 ml	150 ml
Head Computed Tomography	50-150 ml	150 ml
Body Computed Tomography	25-150 ml	150 ml
Intraarterial Digital Subtraction Angiography	5-80 ml	250 ml
Intravenous Digital Subtraction Angiography	30-50 ml	250 ml

* Repeated as necessary

Elderly
Dosage as for adults. Where poor demonstration is to be expected, the dosage can be increased to the maximum.

It is recommended that Optiray 350 PFS is warmed up to body temperature prior to injection. As with all radiopaque contrast agents, the lowest dose necessary to obtain adequate visualisation should be used.

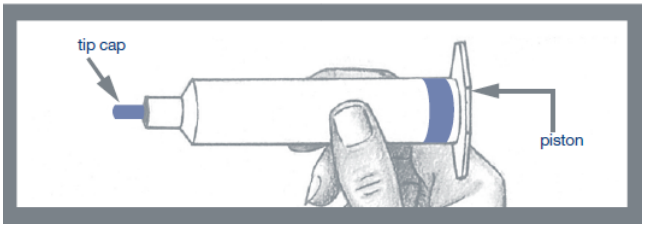
Discard if the solution is markedly discoloured or is not clear of particulate matter.

Optiray 350 PFS is supplied in single dose containers; discard any unused solution.

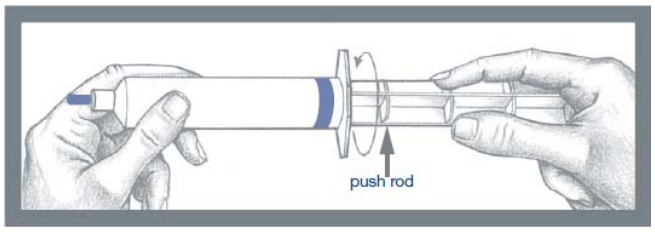
Handling Instructions of Handheld Syringes

Assembly and Inspection:

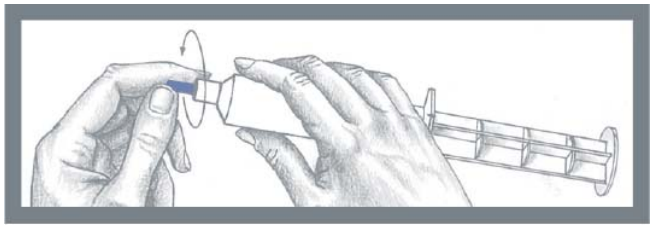
Note: Exterior of syringe is not sterile. Contents of syringe and area under blue tip cap and piston ribs are sterile and should be treated accordingly.



Remove syringe from support and inspect the area around the tip cap and outside of piston for signs of leakage. Do not use if leakage is observed.



After screwing the push rod into the syringe piston, it is important to turn the push rod an additional 1/2 turn so that the blue piston rotates freely.



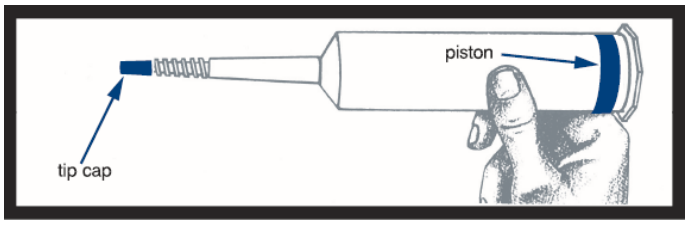
Prior to using the syringe, twist off blue tip cap and discard. The area under the tip cap is sterile, caution should now be used when handling. Syringe is now ready for needle or infusion tubing attachment.

Discard syringe and unused portion of medium after use.

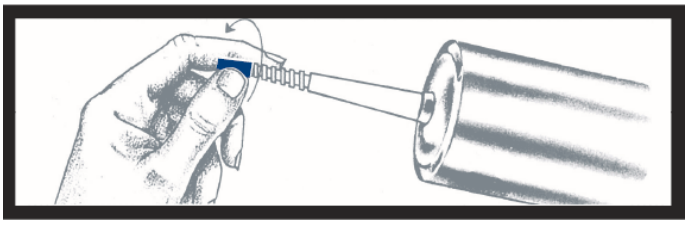
Handling Instructions of Power Injector Syringes

Assembly and Inspection:

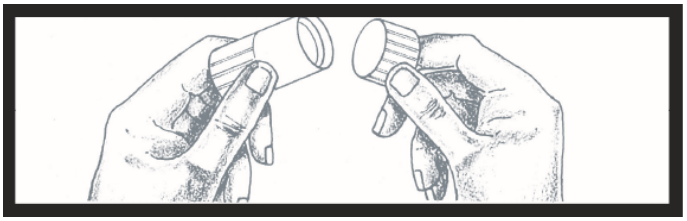
Note: Exterior of syringe is not sterile. Contents of syringe and area under blue tip cap and piston ribs are sterile and should be treated accordingly.



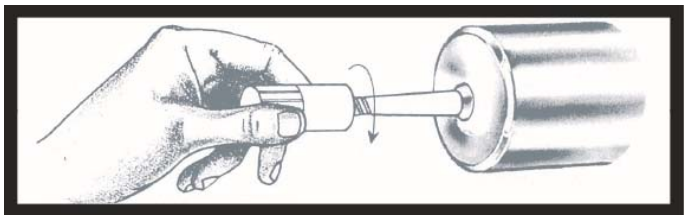
Remove syringe from support and inspect the area around the tip cap and outside of piston for signs of leakage. Do not use if leakage is observed. Load syringe into pressure jacket.



To remove blue tip cap from syringe, push in and twist off, then discard. The area under the cap is sterile. Caution should now be used when handling.



Next remove cap from luer locknut dust cover by twisting to break tamper evident seal. Discard cap.



Attach luer locknut to syringe by holding dust cover and screwing to the stop. Remove and discard dust cover when ready to attach sterile connector tubing.

Discard syringe and unused portion of medium after use.