Optiray® 240 (Ioversol Injection 51% W/V) Optiray® 320 (Ioversol Injection 68% W/V) Optiray® 350 (Ioversol Injection 74% W/V)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about OPTIRAY. It does not contain all the available information. It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of using OPTIRAY against the benefits it is expected to have for you.

If you have any concerns about receiving OPTIRAY, ask your doctor.

Keep this leaflet.
You may need to read it again.

In this leaflet:

1. What is OPTIRAY and what it is used for

OPTIRAY is an injectable contrast medium. It is used to make clearer diagnostic images of the brain and body in adults and children. As a result, it helps to clearly show abnormalities in the brain or body. This medicine is for diagnostic use only.

2. Before you are given OPTIRAY

When you must not use it

Do not use OPTIRAY if you are allergic (hypersensitive):

- to the active substance ioversol, or
- to any of the other ingredients in OPTIRAY

Take special care with OPTIRAY

Diagnostic procedures involving the use of contrast agents should be conducted under supervision of a physician with the prerequisite training and a thorough knowledge of the procedure to be performed.

Before you start to use it

Tell your doctor if:

- you suffer from allergies (e.g. medicinal products, seafood, hay fever, hives) or asthma
- you had any reaction to previous injections of a contrast agent, including a previous history of reaction to iodine-based agents
- your kidneys do not function properly
- OPTIRAY is planned to be used in your child who is under the age of two years

Tell your doctor if:

- you are feeling thirst and/or you have only had small quantities or nothing to drink before the examination
- you have a cardiac pacemaker or any ferromagnetic implant (vascular clips, etc.) or a metallic stent in your body
- you are taking a special kind of antihypertensive medicine, i.e. a beta-blocker
- you have heart disease

- you suffer from epilepsy or brain lesions
- you are or your child is on a controlled sodium diet
- If any of these apply to you, your doctor will decide whether the intended examination is possible or not.

Using other medicines

Please tell your doctor if you are taking or have recently taken any other medicines including medicines obtained without a prescription from your pharmacy, supermarket or health food shop.

Pregnancy and breast feeding
It is not known whether OPTIRAY is excreted in human milk. Tell your doctor if you are pregnant and ask your doctor for advice before you are given OPTIRAY.

Driving and using machines
If you are an ambulant patient and plan to drive or use tools or machines, take into account that dizziness may incidentally occur after you undergo a procedure involving the injection of OPTIRAY.

Important information about some of the ingredients of OPTIRAY
This medicine contains the following ingredients in each mL of OPTIRAY. Please refer to the table below.

	OPTIRAY 240	OPTIRAY 320	OPTIRAY 350
Ioversol content (mg/mL)	509	678	741
Iodine content (mg/mL)	240	320	350
Sodium calcium edetate as a stabiliser (mg/mL)	0.2	0.2	0.2
Tromethamine (mg/mL)	3.6	3.6	3.6

3. How OPTIRAY is given

The usual dose

Your doctor will decide how much you will be given. This depends on your condition and other factors. Patients should be well hydrated prior to and following the administration of OPTIRAY.

4. When you are given OPTIRAY

Things to be careful of

This medicine may cause dizziness, lightheadedness, tiredness or drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. Children should be careful when riding bicycles or climbing trees.

If you feel lightheaded, dizzy or faint when getting out of bed or standing up, get up slowly.
Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

If you are given more OPTIRAY than you should have been (overdose)

Overdosage may occur. The adverse effects of overdosage are potentially life-threatening and affect mainly the pulmonary, cardiovascular system and central nervous systems. Treatment of an overdose is directed toward the support of all vital functions and prompt institution of symptomatic therapy. OPTIRAY does not bind to plasma or serum proteins and is therefore dialysable.

If you have any further questions or concerns on the use of this medicine, ask your doctor or pharmacist.

The following adverse effects have occurred in conjunction with the administration of iodinated intravascular contrast agents for this purpose: low blood pressure, shock, chest pains, cardiac arrest, slow heart rate, abnormally rapid heart rhythm, death. Severe adverse reactions, especially abnormal heart rhythms, are likely to occur with greater frequency following right coronary artery injection. Fatalities have been reported.

Some paediatric patients have a higher risk of adverse reactions to contrast media. Such patients may include those with sensitivity to allergens, including other drugs,those with asthma, congestive heart failure, a serum creatinine 1.5 mg/dL, or ages under 12 months.

Immediately tell the doctor or nurse/technologist who is giving you the injection, if you feel unwell, especially if you feel any tightness, pain or discomfort in your chest, face or throat, or you have difficulty breathing.

5. Possible side effects

Very common	In more than 1 of 10 treated patients
Common	In less than 1 of 10, but more than 1 of 100 treated patients
Uncommon	In less than 1 of 100, but more than 1 of 1000 treated patients
Rare	In less than 1 of 1000, but more than 1 of 10,000 treated patients
Very rare	In 1 case or less than 10,000 treated patients including isolated reports

Frequency	Possible side effects
Very common	None
Common	Flush and general pain
Uncommon	Nausea, vomiting and rash/hives
Rare	Low blood pressure, numbness or tingling sensation, nasal congestion, sneezing, coughing, itching, shaking chills and bad taste
Very rare	Chest pains, slow heart rate, high blood pressure, fainting, headache, blurred vision, dizziness, lightheadedness, disorientation, visual hallucination, swelling and fluid retention in the face, legs or feet, difficulty breathing or swallowing

6. Product Description

Ingredients:

- The active substance is ioversol.
- 1 mL contains 509 to 741 mg of ioversol, depending on the concentration of OPTIRAY being administered.
- The other ingredients are: sodium calcium edetate , Trometamol, trometamol hydrochloride, sodium hydroxide and/or hydrochloric acid, and water for injections.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What OPTIRAY looks like and contents of the pack

OPTIRAY contains a clear, colourless to pale yellow solution.

OPTIRAY is supplied in vials fitted with bromobutyl rubber closures and aluminium cap seals.

OPTIRAY is supplied in prefilled syringes made of polypropylene. Syringe tip cap and piston are made of bromobutyl rubber.

OPTIRAY is supplied in packs of 10 units. The following concentrations are available:

OPTIRAY 240

- 30 mL injection vial AUST R 15326
- 50 mL injection vial AUST R 49410
- Ultraject® 50 mL injection syringe AUST R 46639
- Ultraject® 125 mL injection syringe AUST R 46640

OPTIRAY 320

- 20 mL injection vial AUST R 20034
- 30 mL injection vial AUST R 49421
- 50 mL injection vial AUST R 49422
- 100 mL injection vial AUST R 49423
- 150 mL injection vial AUST R 49424
- 200 mL injection vial AUST R 49425
- Ultraject® 50 mL injection syringe AUST R 46641
- Ultraject® 125 mL injection syringe AUST R 46642
- Ultraject® 75 mL injection syringe AUST R 73580

OPTIRAY 350

- 20 mL injection vial AUST R 49610
- 30 mL injection vial AUST R 47856
- 50 mL injection vial AUST R 47996
- 75 mL injection vial AUST R 47997
- 100 mL injection vial AUST R 47998
- 150 mL injection vial AUST R 49611
- 200 mL injection vial AUST R 49612
- Ultraject® 30 mL injection syringe AUST R 51795
- Ultraject® 50 mL injection syringe AUST R 51796
- Ultraject® 75 mL injection syringe AUST R 70059
- Ultraject® 100 mL injection syringe AUST R 61983
- Ultraject® 125 mL injection syringe AUST R 61984

Not all presentations may be marketed.

Do not use the solution if it is discoloured or particulate material is present.

Sponsor

For any information about this medicine, please contact the sponsor:

Guerbet Australia Pty Ltd
166 Epping Road
Lane Cove, NSW 2066
Australia

This leaflet was prepared in June 2016.