

OPTIRAY® 320 (Ioversol Injection 68% w/v) Solution for Injection

OPTIRAY® 350 (Ioversol Injection 74% w/v) Solution for Injection

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I given OPTIRAY?

OPTIRAY contains the active ingredient ioversol. OPTIRAY is used for diagnostic examinations only.

For more information, see Section [1. Why am I given OPTIRAY?](#) in the full CMI.

2. What should I know before I am given OPTIRAY?

You must not be given OPTIRAY if you are allergic to the active ingredient (ioversol) or any of the ingredients listed at the end of the CMI. You must not be given OPTIRAY if you have an overactive thyroid gland; unable to pass urine or pass very little urine.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I am given OPTIRAY?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with OPTIRAY and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How am I given OPTIRAY?

Diagnostic examinations involving the use of contrast agents should be conducted under the supervision of a doctor with the prerequisite training and a thorough knowledge of the examination to be performed. More instructions can be found in Section 4. How am I given OPTIRAY? in the full CMI.

5. What should I know while receiving OPTIRAY?

Things you should do	<p>Tell your doctor if you:</p> <ul style="list-style-type: none">• Suffer from asthma or allergies• Had previous reactions to injections of contrast agents• Have kidney or liver disease; or have diabetes• Have heart failure, high blood pressure, circulation disorders, had a stroke, and if you are elderly• Have brain disorders; red blood cell abnormality; problems with bone marrow (e.g. multiple myeloma)• Have a tumour of the adrenal gland known as paraproteinaemia, which affects your blood pressure• Have a child under 12 months of age; you are, or intend to be, pregnant or breast-feeding• Are feeling thirst and/or have only had small quantities (or nothing) to drink before examination• Have a cardiac pacemaker or any ferromagnetic implant (vascular clips, etc.) or a metallic stent in body• Are taking antihypertensive medicines known as beta-blockers• Are, or your child is, on a controlled sodium diet
Driving or using machines	<ul style="list-style-type: none">• Driving or operating machines is not advisable for up to 1 hour after injection. Symptoms such as dizziness, drowsiness, fatigue and visceral disturbances have been reported
Looking after your medicine	<ul style="list-style-type: none">• The clinic where the diagnostic examination is done will store OPTIRAY as recommended by the manufacturer.

For more information, see Section [5. What should I know while receiving OPTIRAY?](#) in the full CMI.

6. Are there any side effects?

Serious side effects include irregular heartbeat or breathing, heart vessel spasms or blood clots, stroke, blue lips, fainting, loss of memory, speech disorder, sudden movements, temporary blindness, acute kidney failure, skin rash, redness or blisters, signs of allergic reactions such as allergic shock, tightened airways, swelling of the throat or tongue.

CMI. OPTIRAY®

Active ingredient(s): *ioversol*

Consumer Medicine Information (CMI)

This leaflet provides important information about using OPTIRAY. **You should also speak to your doctor or nurse if you would like further information or if you have any concerns or questions about using OPTIRAY.**

Where to find information in this leaflet:

- [1. Why am I given OPTIRAY?](#)
- [2. What should I know before I am given OPTIRAY?](#)
- [3. What if I am taking other medicines?](#)
- [4. How am I given OPTIRAY?](#)
- [5. What should I know while receiving OPTIRAY?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I given OPTIRAY?

OPTIRAY contains the active ingredient ioversol. OPTIRAY is an injectable contrast medium containing iodine. It is used to make clearer diagnostic images of the brain and body in adults and children. The iodine blocks the X-rays, allowing vessels and the inner organs supplied with blood to be seen. As a result, it helps to clearly show abnormalities in the brain or body

OPTIRAY is for diagnostic examinations only.

2. What should I know before I am given OPTIRAY?

Warnings

Do not use OPTIRAY if:

- you are allergic (hypersensitive) to the active ingredient ioversol, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- You have an overactive thyroid gland or high levels of thyroid hormones.
- You are unable to pass urine or pass very little urine.

Check with your doctor or nurse if you:

- have any other medical conditions such as:
 - asthma or allergies (e.g. medicinal products, seafood, hay fever, hives)
 - kidney or liver disease
 - diabetes
 - heart failure, high blood pressure, circulation disorders, or had a stroke, and if you are elderly
 - brain disorders

- problems with bone marrow, such as blood cancers known as paraproteinaemia or multiple myeloma
- red cell abnormality known as sickle cell anaemia
- tumour of the adrenal gland known as pheochromocytoma, which affects your blood pressure
- have a child under the age of 12 months and OPTIRAY is planned for the examination
- pregnant or intend to become pregnant. If you receive this medicine whilst pregnant, your newborn should be tested to ensure they are producing the correct amount of thyroid hormone.
- breast-feeding or plan to breast-feed
- feeling thirst and/or have only had small quantities or nothing to drink before the examination
- have a cardiac pacemaker or any ferromagnetic implant (vascular clip, etc.) or a metallic stent in your body
- you are taking any antihypertensive medicine, known as beta-blocker
- you or your child is on a controlled sodium diet.
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor or nurse if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or nurse if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with OPTIRAY and affect how it works. Tell your doctor if you are taking any of the following medicines:

- Metformin, used to treat diabetes
- Interleukins, used to treat certain tumours
- Vasopressors, used to increase blood pressure
- Diuretics, used to help eliminate salt and water from your body

Check with your doctor or nurse if you are not sure about what medicines, vitamins or supplements you are taking and if these affect OPTIRAY.

4. How am I given OPTIRAY?

How much is given

- Your doctor will decide how much you will be given. The dosage of OPTIRAY depends on your condition, the specific examination you are having and other factors such your health and age.
- The lowest possible dose will be given to produce adequate X-ray images.

How OPTIRAY is given

Diagnostic examinations involving the use of contrast agents should be conducted under the supervision of a doctor with the prerequisite training and a thorough knowledge of the examination to be performed.

If you are given too much OPTIRAY

It is highly unlikely that you will receive too much OPTIRAY as it will be given by a trained healthcare professional.

Overdosages are potentially life-threatening and may affect breathing, heart and circulation system. Inform your doctor immediately if you notice any of those symptoms after receiving OPTIRAY.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while receiving OPTIRAY?

Things you should do

You should be well hydrated prior to and following the administration of OPTIRAY.

You should get up slowly. Standing up slowly, especially when you get up from bed or chair, will help your body get used to the change in position and blood pressure. If the problem continues or gets worse, talk to your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how OPTIRAY affects you.

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

Children should be careful when riding bicycles or climbing trees.

Looking after your medicine

As this is being given to you by your doctor, it is extremely unlikely that you will be expected to look after the injection. However, in the case that you may have to transport it from the pharmacy to your doctor, keep the container in the outer carton to protect from light. Do not store below 25°C.

Do not use this medicine if the packaging is torn or shows signs of tampering or after the expiry date which is stated on the label.

Do not use the solution if it is discoloured or particulate material is present. This medicine should only be used once. Discard unused contents.

Keep it where young children cannot reach it.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or nurse if you have any further questions about side effects.

Side effects with OPTIRAY in most cases are mild to moderate, they are very rarely serious or life-threatening.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">FlushFeeling hot	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">Signs of allergic reactions, such as allergic shock, tightened airways, swelling of the throat or tongue, breathing difficulties, cough, sneezing, reddening and/or swelling of the face and eyes, itching, rash, and hives.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 which causes rash, fever, inflammation of internal organs,	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

<p>haemological abnormalities and systemic illness (DRESS).</p> <ul style="list-style-type: none"> • Irregular heartbeat, heart vessel spasms or blood clots • Stroke, blue lips, fainting • Loss of memory • Speech disorders • Sudden movements • Temporary blindness • Acute kidney failure 	
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Immediately tell the doctor or other healthcare professional 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 if you have difficulty breathing.
- Feel lightheaded, dizzy or faint when getting out of bed or standing up.

Side-effects in Children

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

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

What OPTIRAY contains

Active ingredient (main ingredient)	loversol
Other ingredients (inactive ingredients)	Sodium calcium edetate Trometamol Trometamol hydrochloride Sodium hydroxide Hydrochloride acid Water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What OPTIRAY looks like

OPTIRAY is a clear, colourless to pale yellow solution.

OPTIRAY is available in glass vials or plastic pre-filled syringes (PFS).

The following OPTIRAY packs are registered:

OPTIRAY 320

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

OPTIRAY 350

- 20 mL vial – AUST R 49610
- 30 mL vial – AUST R 47856
- 50 mL vial - AUST R 47996
- 75 mL vial - AUST R 47997
- 100mL vial - AUST R 47998
- 150 mL vial - AUST R 49611
- 200 mL vial - AUST R 49612
- 500 mL vial - AUST R 320145
- 30 mL Ultraject® injection syringe – AUST R 51795
- 50 mL Ultraject® injection syringe – AUST R 51796
- 75 mL Ultraject® injection syringe – AUST R 70059
- 100 mL Ultraject® injection syringe – AUST R 61983
- 125 mL Ultraject® injection syringe – AUST 61984

OPTIRAY vials are available in packs of 10 or 25 units.

OPTIRAY 350 in 500 mL vials are available in packs of 5, 6 or 10 units.

OPTIRAY prefilled syringes are available in packs of 10 or 20 units.

Not all strengths and pack sizes may be available.

Who distributes OPTIRAY

Guerbet Australia Pty Ltd

166 Epping Road,

Lane Cove West NSW 2066

Australia

This leaflet was prepared in July 2025.