

## Prescribing information

### Optiray™ Ioversol

**Abbreviated Prescribing Information. Please refer to the Summary of Product Characteristics before prescribing. COMPOSITION:** O1610050UK – OPTIRAY™ 160 Ioversol, 339 mg/ml which is equivalent to 160 mg/ml of elemental iodine. O2410050UK – OPTIRAY™ 240 Ioversol, 509 mg/ml, which is equivalent to 240 mg/ml of elemental iodine. O3010050UK – OPTIRAY™ 300 Ioversol, 636 mg/ml, which is equivalent to 300 mg/ml of elemental iodine. O3210050UK – OPTIRAY™ Ioversol, 678 mg/ml, which is equivalent to 320 mg/ml of elemental iodine. O3510050UK – OPTIRAY™ Ioversol, 741 mg/ml, which is equivalent to 350 mg/ml of elemental iodine. **INDICATIONS:** OPTIRAY™ non-ionic X-ray contrast medium for injection or infusion. Depending on the preparation, it is indicated for use in cerebral, coronary, peripheral, visceral and renal angiography, in aortography, left ventriculography, venography, intravenous excretory urography and computed tomography (CT) of the head and body. Except for OPTIRAY™ 300, safety and effectiveness of OPTIRAY™ in children has not yet been established. **POSOLGY AND METHOD OF ADMINISTRATION:** The dosage of OPTIRAY™ depends on the patient, the contrast medium concentration, the type of investigation and the technique used. It may vary between 1 ml and 150 ml, maximum total dose 250 ml or less. Please refer to the Summary of Product Characteristics for the recommended dosage schedule. **CONTRAINDICATIONS:** Proven hypersensitivity to iodine-containing contrast media. Manifest hyperthyroidism. **SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE:** As with all other X-ray contrast media, OPTIRAY™ may cause anaphylaxis or other manifestations of pseudo-allergic intolerance reactions, e.g. nausea, vomiting, dyspnoea, erythema, urticaria and hypotension. Pre-testing cannot be relied upon to predict severe reactions. The thorough assessment of the medical history of the specific patient may be more accurate in predicting potential adverse reactions. A positive history of allergy is not a contraindication, but does require caution. Diagnostic procedures, which involve the use of iodinated intravascular contrast agents, should be performed under the direction of personnel skilled and experienced in the particular procedure to be performed. Serious or fatal reactions have been associated with the administration of iodinated X-ray contrast media. 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 for at least 30 to 60 minutes after administration. Patients with congestive heart failure should be observed for several hours following the procedure to detect delayed haemodynamic disturbances, which may be associated with a transitory increase in the circulating osmotic load. All other patients should be observed for at least one hour after the application, as it has been reported that most of the adverse events occur in this period. The patient should also be formed that allergic reactions may develop up to several days post administration; in such case, a physician should be consulted immediately. Caution must be exercised in patients with severely impaired renal function, combined renal and hepatic disease, anuria, diabetes mellitus, homozygotic sickle cell disease, or monoclonal gammopathy (multiple myeloma, Waldenström's macro-globulinaemia), particularly when large doses are administered. Serious renal effects, including acute renal failure, may occur in these patients. Preparatory dehydration is dangerous and may contribute to acute renal failure. Iodine-containing contrast media may also be hazardous in patients with hyperthyroidism or with autonomous areas of the thyroid gland. In patients with pheochromocytoma a premedication with alpha-blockers is advisable when the contrast medium is administered intravascularly due to the risk of a hypertensive crisis. Serious neurologic events have been observed following direct injection into cerebral arteries or vessels supplying the spinal cord, or in angiocardiology due to inadvertent filling of the carotids. General anaesthesia may be indicated in selected patients. However, a higher incidence of adverse reactions has been reported in these patients, probably due to the hypotensive effect of the anaesthetic. In angiographic procedures, the possibility of dislodging plaque or damaging or perforating the vessel wall should be considered during catheter manipulation and contrast medium injection. In patients with advanced atherosclerosis, serious hypertension, cardiac decompensation, senility, preceding

cerebral thrombosis or embolism, special caution should be exercised. Cardiovascular reactions as bradycardia, rising or falling of blood pressure may occur more often. Angiography should be avoided whenever possible in patients with homocystinuria due to an increased risk of thrombosis and embolism. Optiray™ should be injected with caution to avoid perivascular application. However, significant extravasation of Optiray™ may occur especially during the use of power injectors. Generally, it is tolerated without substantial tissue injury applying conservative treatment. However, serious tissue damage (e.g. ulceration) has been reported in isolated cases requiring surgical treatment. For indication specific warnings, please refer to summary of product characteristics. **INTERACTIONS WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION:** The following interactions have been reported after the administration of other iodinated contrast media. They are generally accepted as being attributable to this class of contrast media. Renal toxicity has been reported in patients with liver dysfunction, who were given oral cholecystographic agents followed by intravascular contrast agents. Administration of any intravascular X-ray contrast agent should therefore be postponed in patients who have recently received a cholecystographic contrast agent. Patients who have been treated with Interleukin may develop a higher rate of adverse reactions. An increased or delayed occurrence of these reactions within a period of 2 weeks was observed after administration of Interleukin. An arterial injection of an X-ray contrast medium should never be made following the administration of vasopressors, since they strongly potentiate neurologic effects. Acute renal failure has been associated with lactic acidosis in patients receiving Metformin at the time of an X-ray examination. If the serum creatinine is normal, the examination should be performed and intake of Metformin stopped from the time of the examination. The use of Metformin should not be resumed for 48 hours, and should only be restarted if renal function/serum creatinine remains within the normal range. Iodinated X-ray contrast media may reduce the capacity of the uptake of iodine by the thyroid gland. For this reason the results of PBI (protein-bound iodine) and radioactive iodine uptake studies, which depend on iodine estimation, will not accurately reflect thyroid function for up to 16 days following administration of iodinated X-ray contrast media. **PREGNANCY AND LACTATION:** No clinical data on exposed pregnancies are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy. Caution should be exercised when prescribing to pregnant women. However, since any X-ray investigation during pregnancy may involve a potential risk, the risk/benefit ratio should be carefully weighed and alternative methods sought where possible. Many injectable contrast agents are excreted unchanged in breast milk to an amount of approximately 1 % of the given dose. Where contrast enhanced X-Ray is imperative, consideration should be given to discontinuing nursing for one day. **EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:** It is not advisable to drive or operate machinery for one hour following the injection. **UNDESIRABLE EFFECTS:** Side effects are usually mild to moderate, of short duration and resolve spontaneously without treatment. Side effects may consist of headache, nausea, vomiting, sensations of heat and pain, hypotension and skin rashes. **LEGAL STATUS:** Prescription only **MARKETING AUTHORISATION HOLDER:** Tyco Healthcare UK, 154, Fareham Road, Gosport, Hants. PO13 0AS Tel: 01329 224 159 **PRODUCT LICENCE NUMBERS:** OPTIRAY™ 160 18963/10, OPTIRAY™ 240 18963/11, OPTIRAY™ 300 18963/12, OPTIRAY™ 320 18963/13, OPTIRAY™ 350 18963/14 **LIST PRICES:** O1610050UK OPTIRAY™ 160 10x50ml £95.91; O2410050UK OPTIRAY™ 240 10x50ml £124.26; O3010050UK OPTIRAY™ 300 10x50ml £150.86; O3210050UK OPTIRAY™ 320 10x50ml £165.44; O3510050UK OPTIRAY™ 350 10 x 50ml £180.38 **DATE OF PREPARATION:** 25 Nov 2005 **DATE OF (PARTIAL) REVISION OF THE TEXT:** 16 April 2007 **ADVERSE EVENTS CAN BE REPORTED TO:** Covidien (UK) Commercial Ltd, 154 Fareham Road, Gosport, Hants PO13 0AS. Tel: 01329 224 124 Information on adverse event reporting can be found at [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk). **FURTHER INFORMATION AVAILABLE FROM:** Covidien (UK) Commercial Ltd, 154 Fareham Road, Gosport, Hampshire PO13 0AS Tel: 01329 224000 © Copyright Covidien (UK) Commercial Ltd



**Contrast Media Delivery Solution**  
Optiray™ Ioversol pre-filled contrast medium  
and the Optivantage™ DH injector



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## Features & benefits

- Dual Head for injection with saline**
  - allows sequential injections of contrast medium and saline for a tight bolus of contrast medium
- Touch screen on power head for patient side programming and control**
  - enables you to stay with the patient longer
- Faceplate for pre-filled syringes**
  - for easy loading and removal
- Tilt enable and Air Injection warning**
  - to reduce the risk of air embolus
- Patency Check™ software**
  - Stay at the patient's side to perform a saline flush to check for patent veins and correct placement of cannula
- Timing Bolus™ software**
  - to perform a test injection with contrast for determination of delay time
- Optibolus™ software**
  - bolus shaping software to provide an extended period of uniform vascular enhancement
- Available as ceiling or pedestal mounted**
  - to compliment your CT suite set up



## Take advantage of the Optivantage DH CT injector



## Optimise efficiency

We listened to CT specialists and have specifically designed the Optivantage DH Contrast Delivery System.

With the Optivantage DH CT injector, Covidien brings saline flush capability to your CT procedures. The addition of saline to contrast injections has proven clinical advantages for imaging professionals. The Optivantage DH CT injector features the industry's only fully-programmable powerhead, allowing operators to stay with their patients throughout injection preparation – providing enhanced ease, convenience, speed and patient-side safety.

Together with Optiray\* Ioversol contrast medium pre-filled syringes, Covidien is proud to offer our unique delivery solution, offering you reduced set-up time<sup>3</sup> and increased patient safety!

\*Please see back page for abbreviated prescribing information for Optiray™ Ioversol contrast medium.



## Simplicity and safety

In a busy, modern CT department, with the demands of emergency scans and the capabilities of newer scanning technology, utilising time in a safe and efficient way has never been more important.

Pre-filled syringes can help to eliminate problems which can compromise patient safety.<sup>1</sup>

Pre-labelled to help reduce the risk of radiological errors, pre-filled syringes require no filling from vials which can also help reduce microbial contamination during preparation and can reduce set up time.<sup>3</sup>

The Optivantage DH injector together with Optiray Ioversol contrast medium in pre-filled syringes is specifically designed with the advantages of a pre-filled system in mind to offering a solution to help make your contrast medium delivery simpler and safer and leaving you to spend more time with the patient.

### Optivantage™ DH CT injector & Optiray™ contrast medium pre-filled

Technology and innovation working hand in hand

- Easy to use
- Reduction of air embolisms<sup>3</sup>
- Can help to reduce set up time
- Decreased potential risk of breakage<sup>1</sup>
- Reduced packaging wastage<sup>1</sup>
- Reduction of administration error (injection of incorrect medication and/or dosage)<sup>1</sup>
- Reduce the possibility of contamination<sup>3</sup>
- Faceplate for pre-filled syringes for easy loading and removal
- Reduced risk of extravasation – select and change protocols at the powerhead, where and how you want them

#### References

- <sup>1</sup> Recommendations on the use of contrast media pre-filled syringes in radiology: a roundtable discussion. Hospital Pharmacy Europe. May/June 2007
- <sup>2</sup> David H. Cousins. Patient safety issues with x-ray contrast media. Hospital Pharmacy Europe. January/February 2007
- <sup>3</sup> Enterline D. Examining pre-filled syringes versus bottle-filled cartridges for contrast-enhanced CT examination. A multicenter Time-Efficiency Trial. Decision in Imaging Economics. Feb. 2003

## Speed and efficiency

The advantages of pre-filled systems

### Speed

- Reduces time required for each procedure, optimising patient turnover
- No filling from vials required
- No additional labelling of syringe required
- Reduced set up time<sup>3</sup>

### Safety

- Minimises the risk of misadministration of contrast due to mislabelling
- Reduction of air embolisms
- Reduction of microbial contamination during preparation and administration
- Reduction of breakages
- No filling of empty syringes from vials
- Minimal risk of mislabelling
- No exposed metal ring-pulls

### Efficiency

- Reduced packaging wastage
- No product wastage if appointment cancelled
- Ease of inventory management
- No glass to dispose of

### Care

- Reduced set up time can allow you to spend more time with the patient



## Technical specifications

### Flow Rate

- 0.1 -10.0 ml/sec

### Pressure Limit

- 50- 325 psi

### Syringe Sizes

- 200 ml empty syringes
- 50, 75, 100, 125ml high pressure prefilled syringes

### Syringe Heater

- 37° C nominal
- Minimises the loss of heat from preheated contrast

### Volume

- 0.1 ml to volume in syringe

### Scan Delay

- 0-600 sec

### Inject Delay

- 0-600 sec

### Phase Delay

- 0-600 sec

### Number of Phases

- 6

### Protocol Memory

- 40

### Inject Results

- Last 24 injected protocols

### Total Time Display Parameters

- 0-99:59 (minutes:seconds)

### Programmable Drip Mode

- Parameters (Saline Side)
  - Flow Rate: 0.1 -1.0 ml/s
  - Volume: 0.1 - 3.0 ml
  - Interval: 0 - 60 seconds

### Programmable Patency Check™

- Parameters (Saline Side)
  - Flow Rate: 0.1 -10 ml/s (defaults to maximum flow rate of protocol)
  - Volume: 1 -200 ml
  - Default Volume: 1 -200 ml

### Dimensions

- Console: 311 W x 64 H x 216 D mm
- Console Base: 241 W x 64 H x 178 D mm
- Powerhead: 318 W x 152 H x 203 D mm
- Power Supply: 267 W x 228 D x 102 H mm

### Weight

- Console w/Base: 2.6 kg
- Powerhead: 6.57 kg
- Power Supply: 2.7 kg

### Power Requirements

- Standby: less than 1 A
- Standard: 115 VAC, 4 A, 50/60 Hz;
- 230 VAC, 2 A, 50/60 Hz



## Presentations and concentrations

Summary of Product Characteristics enclosed

Radiology Urology	Radiology Urology	Angiography Radiology Urology	Radiology Urology
Optiray 240*	Optiray 300	Optiray 320*	Optiray 350*
Glass vials			
50ml 100ml	10ml 20ml 50ml 75ml 100ml 150ml	20ml 50ml 75ml 100ml 200ml	30ml 50ml 100ml 200ml
Pre-filled handheld syringes			
50ml	50ml		50ml
Pre-filled high pressure syringes			
75ml 100ml 125ml	75ml 100ml 125ml	50ml	50ml 100ml 125ml

A comprehensive range of procedure based presentations

\*For adults only – Optiray 300 can be used in children