1. NAME OF THE MEDICINAL PRODUCT

Optiray® 350 mg Iodine/ml, Solution for injection or infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of solution contains the following amount of the active substance:

- Ioversol: 350 mg (350 mg Iodine)

3. PHARMACEUTICAL FORM

Solution for injection or infusion. Clear, colourless to faint yellow solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

Optiray® is a non-ionic X-ray contrast medium that is indicated in adults for angiography throughout the cardiovascular system including coronary arteries, cerebral arteries, peripheral arteries and visceral arteries. Optiray® is also indicated in adults for use in computer tomography of the head and body, intravenous urography, venography and intraarterial digital subtraction angiography (IA DSA) and IV DSA.

4.2. Precautions and use of medicinal products

For adults: Recommended dosage schedule

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Dose (ml)</th>
<th>Maximum Total Dose (ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peripheral angiography</td>
<td>5-100</td>
<td>250</td>
</tr>
<tr>
<td>Left ventriculography</td>
<td>1-10</td>
<td>250</td>
</tr>
<tr>
<td>Coronary angiography</td>
<td>1-10</td>
<td>250</td>
</tr>
<tr>
<td>Vascular angiography</td>
<td>4-60</td>
<td>250</td>
</tr>
<tr>
<td>Arteriography</td>
<td>10-80</td>
<td>250</td>
</tr>
<tr>
<td>Renal angiography</td>
<td>10-50</td>
<td>250</td>
</tr>
<tr>
<td>Urography</td>
<td>50-75</td>
<td>250</td>
</tr>
<tr>
<td>Heart CT</td>
<td>50-75</td>
<td>250</td>
</tr>
<tr>
<td>Body CT</td>
<td>25-150</td>
<td>250</td>
</tr>
<tr>
<td>IA DSA</td>
<td>10-40</td>
<td>250</td>
</tr>
<tr>
<td>IV DSA</td>
<td>30-50</td>
<td>250</td>
</tr>
</tbody>
</table>

Dose: As for adults. Where poor demonstration is to be expected, the dose may be increased up to the maximum.

5. Pharmacodynamic and pharmacokinetic properties

Pre-medication with antihistamines and corticosteroids to avoid or minimise allergic reactions should be considered. The possible benefits of such procedures outweigh the risks.

6. Contraindications

Hypersensitivity to iodine-containing contrast media, the active substance, or to any of the excipients listed in section 6.1. Manifest hyperthyroidism. Hypersensitivity to iodine-containing contrast media, the active substance, or to any of the excipients listed in section 6.1. Manifest hyperthyroidism.

7. Undesirable effects

Any of the excipients listed in section 6.1. Manifest hyperthyroidism.

8. Overdose

Telephone: 0123456789

9. Package and labelling

Packaging and labelling

Pack of 10 vials, each containing 1 ml of 350 mg iodine/ml.

10. skeletally matured (see sections 4.3 Contraindications).

11. patients taking general anaesthetics

12. any further questions, ask your doctor or pharmacist.
at 37°C in a contrast media warmer with circulating air.

5. How to store Optiray

www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide

any side effects not listed in this leaflet.

If you get any

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