Dear Customer

**Ioversol, Optiray 300 mg Iodine/ml, solution for injection or infusion**

**100 ml syringe and bottle shortage**

Guerbet in agreement with the MHRA would like to inform you of the following:

**Summary**

- Optiray 300 mg is currently out of stock in UK in syringes and bottles as a consequence of manufacturing site issues.
- UK packs are expected back in stock in May 2020.
- Alternative European sources of the 100 ml bottle are available in non-UK packaging to cover the shortfall between now and May 2020.
- The European products are the same as UK Optiray 300 mg, registered under PL 12308/0028.
- Batch details are provided below. MHRA have authorised the release of these batches.

<table>
<thead>
<tr>
<th>Country</th>
<th>Batch Number</th>
<th>Expiry Date</th>
<th>Pack Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Greece</td>
<td>18J1865</td>
<td>30/09/2021</td>
<td>Box of 100 ml x 1 bottle</td>
</tr>
<tr>
<td></td>
<td>18K2135</td>
<td>31/10/2021</td>
<td></td>
</tr>
<tr>
<td></td>
<td>19E1135</td>
<td>30/04/2022</td>
<td></td>
</tr>
<tr>
<td>Czech Republic</td>
<td>19F1295</td>
<td>31/05/2022</td>
<td>Box of 100 ml x 10 bottles</td>
</tr>
<tr>
<td></td>
<td>18L2465</td>
<td>30/11/2021</td>
<td></td>
</tr>
<tr>
<td>Romania</td>
<td>17E0935</td>
<td>30/04/2020</td>
<td>Box of 100 ml x 10 bottles</td>
</tr>
<tr>
<td>Slovakia</td>
<td>18C0595</td>
<td>28/02/2021</td>
<td>Box of 100 ml x 10 bottles</td>
</tr>
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**Background**

Optiray 300 mg is licenced for diagnostic use only. It is a non-ionic X-ray contrast medium that is indicated in adults for use in cerebral, peripheral and visceral angiography including intraarterial and intravenous digital subtraction angiography (IA-DSA and IV-DSA), venography, intravenous urography, and in computed tomography (CT) of the head and body. Optiray 300 mg may also be used in children for cerebral, peripheral and visceral angiography and for intravenous urography.

To help with the current situation with the shortage of Optiray 300 mg in syringes and bottles, we have been able to acquire a quantity of Optiray 300 bottles that were manufactured for the Greek, Czech Republic, Romanian and Slovak markets.

The Czech Republic, Romanian and Slovak units have the same presentation to the drug marketed in UK (100 ml x 10 bottles). The Greek units are a different pack size (100 ml x 1 bottle), which isn't currently marketed but is registered, in the UK. They are all identical in composition to the UK product and are manufactured in the same facility using the same manufacturing process. The batches to be sent to UK (see table) comply with UK specifications, but their package labelling for sale is different and in the national language.
The brand name Optiray and strength (300) are clearly visible on all non-UK packs, although the word 'Iodine' is not specifically mentioned on the Czech Republic, Romanian or Slovakian packs. Images of the packaging is provided in the Annex.

The registered shelf life and storage conditions are also the same in all countries:-

i.e. "Shelf life: 3 years (unopened). After use, discard the remaining solution. Storage Conditions: Keep the container in the outer carton in order to protect from light. Protect from X-rays. Do not store above 30°C. Optiray can be stored for one month at 37°C in a contrast medium warmer with circulating air. Discard the solution in case of discolouration or particulate matter."

No change to the preparation and/or administration of Optiray 300 mg is required for these non-UK packs.

MHRA have agreed to Batch Specific Variations (BSV) on this product (PL 12308/0028), in order to allow us to sell the following batches in the UK.

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<tr>
<td>Greece</td>
<td>18J1865</td>
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</tr>
</tbody>
</table>

We will provide you with copies of the English language pack insert, comprising both PIL and SmPC text, with each order. Ten pack inserts will be securely attached to each pack of 10 bottles (Czech Republic, Romania and Slovakia), and one to each pack of single Greek bottles. The text is also available on the MHRA website: http://www.mhra.gov.uk/spc-pil/. The cartons have also been over-labelled with UK licenced details.

If both your CT-Radiology and Pharmacy Departments are happy to accept this product, we will liaise with you directly to process specific back-orders you have with us.

**Call for reporting**
Please report any suspected adverse reactions to Guerbet via email (safety@regulis.com) and MHRA via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Please also contact Guerbet’s

**Company contact point**
For further information please contact UK Customer Services Department, Guerbet Laboratories Ltd., Avon House, 435 Stratford Road, Shirley, Solihull, B90 4AA. Email: Uk.info@guerbet.com. Tel. + 44 (0)121 733 8542.

We thank you for you understanding during this stock shortage situation.

Yours faithfully

<Add signature>

Lee Scott
General Manager UK
## ANNEX: Comparison of packaging materials for Optiray 300 mg 100 ml bottles

<table>
<thead>
<tr>
<th>Country</th>
<th>Carton box label (10 x 100 ml bottles)</th>
<th>Bottle label (1 x 100 ml bottle)</th>
<th>Bottle carton (1 x 100 ml bottle)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>UK</strong></td>
<td>[Image]</td>
<td>[Image]</td>
<td></td>
</tr>
<tr>
<td><strong>Greece</strong></td>
<td>[Image]</td>
<td>[Image]</td>
<td>Additional component, not registered in UK or other countries. It is a beige/yellow colour.</td>
</tr>
</tbody>
</table>

### UK

**Optiray® 300 mg Iodine/ml, solution for injection or infusion**

1 ml solution contains 636 mg ioversol, equivalent to 300 mg iodine. Excipients: trometamol, trometamol hydrochloride, sodium calcium edetate, hydrochloric acid, sodium hydroxide and water for injections.

For intravenous injection or infusion. Read the package leaflet before use. For single use only. Discard any unused solution immediately. Protect from light and x-rays, store below 30°C. Keep out of the sight and reach of children.

**PL 12308/0028**

**Guerbet**

Lot O3010100UK

### Greece

**Optiray® 300 mg Iodine/ml, διάλυμα για ένσωση ή εγκύση**

1 ml diaλύματος περίχως 636 mg ioversol, που είναι συστατικό με 300 mg iodine.

Excipients: trometamol, trometamol hydrochloride, sodium calcium edetate, hydrochloric acid, sodium hydroxide and water for injections. For intravenous injection or infusion. Read the package leaflet before use. For single use only. Discard any unused solution immediately. Protect from light and x-rays, store below 30°C. Keep out of the sight and reach of children.

**BP 57400, 59943 Roissy CdG Cedex, France**

Lot L1322GR-B1010-0716

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1 The bottle label is completely white. On this image, the pink colour depicts a cut out area for hanging the bottle, and yellow a non-varnished area where batch LOT/EXP details are printed.
Country: Czech Republic

**Optiray® 300**

**Carton box label (10 x 100 ml bottles)**

10 x 100 ml

- **Country**: Czech Republic
- **Language**: Czech
- **Content**: Details about the product, including the active ingredient, volume, and manufacturing information.

**Bottle label (1 x 100 ml bottle)**

100 ml

- **Country**: Czech Republic
- **Language**: Czech
- **Content**: Detailed description of the product, including usage instructions and dosage information.

**Bottle carton (1 x 100 ml bottle)**

100 ml

- **Country**: Czech Republic
- **Language**: Czech
- **Content**: General information about the product, including packaging and storage instructions.

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Country: Romania

**Optiray® 300**

**Carton box label (10 x 100 ml bottles)**

10 x 100 ml

- **Country**: Romania
- **Language**: Romanian
- **Content**: Information about the product, including the active ingredient and volume.

**Bottle label (1 x 100 ml bottle)**

100 ml

- **Country**: Romania
- **Language**: Romanian
- **Content**: Detailed information about the product, including dosage and usage instructions.

**Bottle carton (1 x 100 ml bottle)**

100 ml

- **Country**: Romania
- **Language**: Romanian
- **Content**: General information about the product, including packaging and storage details.

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Country: Slovakia

**Optiray® 300**

**Carton box label (10 x 100 ml bottles)**

10 x 100 ml

- **Country**: Slovakia
- **Language**: Slovak
- **Content**: Details about the product, including the active ingredient and volume.

**Bottle label (1 x 100 ml bottle)**

100 ml

- **Country**: Slovakia
- **Language**: Slovak
- **Content**: Detailed information about the product, including dosage and usage instructions.

**Bottle carton (1 x 100 ml bottle)**

100 ml

- **Country**: Slovakia
- **Language**: Slovak
- **Content**: General information about the product, including packaging and storage details.