

<Guerbet headed paper>

<Date to be added once BSV approved by MHRA>

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.**

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

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.

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

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 your 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

Country	Carton box label (10 x 100 ml bottles)	Bottle label (1 x 100 ml bottle) ¹	Bottle carton (1 x 100 ml bottle)
UK	<div><p>Optiray® 300 mg Iodine/ml, solution for injection or infusion Ioversol • Non-ionic x-ray contrast medium 10 x 100 ml</p><p>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 intravascular 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.</p><p>PL 12308/0028 Guerbet BP 57400, 95943 Roissy CdG Cedex, France</p><p>Lot EXP</p><p>POM</p><p>Q3010100UK L1332GB-B1010-0716</p></div>	<div><p>Optiray® 300 mg Iodine/ml, solution for injection or infusion Ioversol • Non-ionic x-ray contrast medium 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 intravascular 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.</p><p>Optiray® 300 mg Iodine/ml, solution for injection or infusion Ioversol • Non-ionic x-ray contrast medium 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 intravascular 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.</p><p>Optiray® 300 mg Iodine/ml, solution for injection or infusion Ioversol • Non-ionic x-ray contrast medium 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 intravascular 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.</p></div>	
Greece	<div><p>Optiray® 300 mg Iodine/ml, διάλυμα για ένεση ή έγχυση Ioversol • Μη ιοντικό, ακτινογραφικό, σκιαγραφικό μέσο 10 x 100 ml</p><p>Το 1 ml διαλύματος περιέχει 636 mg Ioversol, που είναι ισοδύναμο με 300 mg ιωδίου. Εκδόχα: trometamol, trometamol hydrochloride, sodium calcium edetate, hydrochloric acid, sodium hydroxide και water for injections. Για ενδοφλέβια ένεση ή έγχυση. Διαβάστε το φύλλο οδηγιών πριν από τη χορήγηση. Για επάπαξ χρήση μόνο. Απορρίψτε κάθε αχρησιμοποίητο διάλυμα αμέσως. Να προστατεύεται από το φως και τις ακτίνες X, φυλάσσεται σε θερμοκρασία μικρότερη των 30°C. Να φυλάσσεται σε θέση την οποία δεν βλέπουν και δεν προσεγγίζουν τα παιδιά. Φαρμακευτικό προϊόν για το οποίο απαιτείται ιατρική συνταγή. Αρ. Αδείας Κυκλοφορίας 33650/18-05-2007 Guerbet BP 57400, 95943 Roissy CdG Cedex, Γαλλία</p><p>Παρεχόμενα ΑΠΕΧΕ</p><p>Guerbet</p><p>Q3010100GR L1332GR-B1010-0716</p></div>	<div><p>Optiray® 300 mg Iodine/ml, διάλυμα για ένεση ή έγχυση Ioversol • Μη ιοντικό, ακτινογραφικό, σκιαγραφικό μέσο Το 1 ml διαλύματος περιέχει 636 mg Ioversol, που είναι ισοδύναμο με 300 mg ιωδίου. Εκδόχα: trometamol, trometamol hydrochloride, sodium calcium edetate, hydrochloric acid, sodium hydroxide και water for injections. Για ενδοφλέβια ένεση ή έγχυση. Διαβάστε το φύλλο οδηγιών πριν από τη χορήγηση. Για επάπαξ χρήση μόνο. Απορρίψτε κάθε αχρησιμοποίητο διάλυμα αμέσως. Να προστατεύεται από το φως και τις ακτίνες X, φυλάσσεται σε θερμοκρασία μικρότερη των 30°C. Να φυλάσσεται σε θέση την οποία δεν βλέπουν και δεν προσεγγίζουν τα παιδιά. Φαρμακευτικό προϊόν για το οποίο απαιτείται ιατρική συνταγή. Αρ. Αδείας Κυκλοφορίας 33650/18-05-2007 Guerbet BP 57400, 95943 Roissy CdG Cedex, Γαλλία</p><p>Optiray® 300 mg Iodine/ml, διάλυμα για ένεση ή έγχυση Ioversol • Μη ιοντικό, ακτινογραφικό, σκιαγραφικό μέσο Το 1 ml διαλύματος περιέχει 636 mg Ioversol, που είναι ισοδύναμο με 300 mg ιωδίου. Εκδόχα: trometamol, trometamol hydrochloride, sodium calcium edetate, hydrochloric acid, sodium hydroxide και water for injections. Για ενδοφλέβια ένεση ή έγχυση. Διαβάστε το φύλλο οδηγιών πριν από τη χορήγηση. Για επάπαξ χρήση μόνο. Απορρίψτε κάθε αχρησιμοποίητο διάλυμα αμέσως. Να προστατεύεται από το φως και τις ακτίνες X, φυλάσσεται σε θερμοκρασία μικρότερη των 30°C. Να φυλάσσεται σε θέση την οποία δεν βλέπουν και δεν προσεγγίζουν τα παιδιά. Φαρμακευτικό προϊόν για το οποίο απαιτείται ιατρική συνταγή. Αρ. Αδείας Κυκλοφορίας 33650/18-05-2007 Guerbet BP 57400, 95943 Roissy CdG Cedex, Γαλλία</p></div>	<div><p>Additional component, not registered in UK or other countries. It is a beige/yellow colour.</p><p>Optiray® 300 mg Iodine/ml, διάλυμα για ένεση ή έγχυση Ioversol • Μη ιοντικό, ακτινογραφικό, σκιαγραφικό μέσο Το 1 ml διαλύματος περιέχει 636 mg Ioversol, που είναι ισοδύναμο με 300 mg ιωδίου. Εκδόχα: trometamol, trometamol hydrochloride, sodium calcium edetate, hydrochloric acid, sodium hydroxide και water for injections. Για ενδοφλέβια ένεση ή έγχυση. Διαβάστε το φύλλο οδηγιών πριν από τη χορήγηση. Για επάπαξ χρήση μόνο. Απορρίψτε κάθε αχρησιμοποίητο διάλυμα αμέσως. Να προστατεύεται από το φως και τις ακτίνες X, φυλάσσεται σε θερμοκρασία μικρότερη των 30°C. Να φυλάσσεται σε θέση την οποία δεν βλέπουν και δεν προσεγγίζουν τα παιδιά. Φαρμακευτικό προϊόν για το οποίο απαιτείται ιατρική συνταγή. Αρ. Αδείας Κυκλοφορίας 33650/18-05-2007 Guerbet BP 57400, 95943 Roissy CdG Cedex, Γαλλία</p><p>Optiray® 300 mg Iodine/ml, διάλυμα για ένεση ή έγχυση Ioversol • Μη ιοντικό, ακτινογραφικό, σκιαγραφικό μέσο Το 1 ml διαλύματος περιέχει 636 mg Ioversol, που είναι ισοδύναμο με 300 mg ιωδίου. Εκδόχα: trometamol, trometamol hydrochloride, sodium calcium edetate, hydrochloric acid, sodium hydroxide και water for injections. Για ενδοφλέβια ένεση ή έγχυση. Διαβάστε το φύλλο οδηγιών πριν από τη χορήγηση. Για επάπαξ χρήση μόνο. Απορρίψτε κάθε αχρησιμοποίητο διάλυμα αμέσως. Να προστατεύεται από το φως και τις ακτίνες X, φυλάσσεται σε θερμοκρασία μικρότερη των 30°C. Να φυλάσσεται σε θέση την οποία δεν βλέπουν και δεν προσεγγίζουν τα παιδιά. Φαρμακευτικό προϊόν για το οποίο απαιτείται ιατρική συνταγή. Αρ. Αδείας Κυκλοφορίας 33650/18-05-2007 Guerbet BP 57400, 95943 Roissy CdG Cedex, Γαλλία</p></div>

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	Carton box label (10 x 100 ml bottles)	Bottle label (1 x 100 ml bottle) ¹	Bottle carton (1 x 100 ml bottle)
Czech Republic	<p>Optiray® 300 Injekční roztok Ioversolum Neionická rentgenová kontrastní látka 10x100 ml</p> <p>1 ml roztoku obsahuje Ioversolum 636 mg (odpovídá 300 mg jódu/ml). Pomocné látky: trometamol, trometamol-hydrochlorid, natrium-kalcium-edetát, kyselina chlorovodíková 1 mol/l anebo roztok hydroxidu sodného 1 mol/l k úpravě pH 6-7,4, voda na injekci. K intravenóznímu nebo intraarteriálnímu podání. Uchovávejte při teplotě do 30°C. Uchovávejte vnitřní obal v krabičce. Chraňte před RTG zářením. Nezmrazujte. Před použitím si přečtěte příbalovou informaci. Uchovávejte mimo dohled a dosah dětí. Výdej léčivého přípravku vázán na lékařský předpis. Nepoužitelné léčivo vraťte do lékárny.</p> <p>Registrační číslo: 48/890/92-C/C</p> <p>Guerbet BP 57400, 95943 Roissy CdG Cedex, France</p> <p>Č. l.: Guerbet</p> <p>Použitelnost do: L1332CZ-B1010-0716 O3010100CZ</p>	<p>Optiray® 300 Injekční roztok</p> <p>Ioversolum Neionická rentgenová kontrastní látka Celkový obsah jódu 30 g. 1 ml roztoku obsahuje Ioversolum 636 mg (odpovídá 300 mg jódu/ml). Pomocné látky: trometamol, trometamol-hydrochlorid, natrium-kalcium-edetát, kyselina chlorovodíková 1 mol/l anebo roztok hydroxidu sodného 1 mol/l k úpravě pH 6-7,4, voda na injekci. K intravenóznímu nebo intraarteriálnímu podání. Uchovávejte při teplotě do 30°C. Uchovávejte vnitřní obal v krabičce. Chraňte před RTG zářením. Nezmrazujte. Před použitím si přečtěte příbalovou informaci. Uchovávejte mimo dohled a dosah dětí. Výdej léčivého přípravku vázán na lékařský předpis. Nepoužitelné léčivo vraťte do lékárny.</p> <p>Registrační číslo: 48/890/92-C/C</p> <p>Guerbet</p>	
Romania	<p>Optiray® 300 10 x 100 ml soluție injectabilă/perfuzabilă 636 mg/ml Ioversol - Mediu de contrast radiologic non-ionic</p> <p>1 ml de soluție conține Ioversol 636 mg, echivalent cu 300 mg iod. Excipienți: trometamol, clorhidrat de sodiu și calciu, acid clorhidric, hidroxid de sodiu și apă pentru preparate injectabile. Pentru administrare intravasculară prin injecție sau perfuzie. A se citi prospectul înainte de utilizare. De unică folosință. A se elimina imediat orice cantitate de soluție neutilizată. A se proteja de lumină și raze X, a se păstra la temperaturi sub 30°C. A nu se lăsa la vedere și îndemâna copiilor. Medicament eliberat pe bază de prescripție medicală-PR.</p> <p>Guerbet 8364/2015/10 BP 57400 95943 Roissy CdG Cedex, Franța</p> <p>Serie: O3010100RO Data expirării: L1332RO-B100-0716</p> <p>Guerbet</p>	<p>Optiray® 300 soluție injectabilă/perfuzabilă 636 mg/ml</p> <p>Ioversol - Mediu de contrast radiologic non-ionic 1 ml de soluție conține Ioversol 636 mg, echivalent cu 300 mg iod. Excipienți: trometamol, clorhidrat de sodiu și calciu, acid clorhidric, hidroxid de sodiu și apă pentru preparate injectabile. Pentru administrare intravasculară prin injecție sau perfuzie. A se citi prospectul înainte de utilizare. De unică folosință. A se elimina imediat orice cantitate de soluție neutilizată. A se proteja de lumină și raze X, a se păstra la temperaturi sub 30°C. A nu se lăsa la vedere și îndemâna copiilor. Medicament eliberat pe bază de prescripție medicală-PR.</p> <p>8364/2015/10</p> <p>Guerbet</p>	
Slovakia	<p>Optiray® 300 injekčný roztok Léčivo: Ioversolum Neiónová rtg. kontrastná látka. 10 x 100 ml</p> <p>1 ml obsahuje Ioversolum 636 mg (zodpovedá 300 mg jódu/ml). Pomocné látky: trometamol, trometamoliumchlorid, edetát sodno-vápenatý, voda na injekcie. Na intravaskulárnu injekciu alebo infúziu. Uchovávať vnútorný obal v škatuľke. Chrániť pred RTG žiarením. Uchovávať pri teplote do 30°C. Nezmrazovať. Prečítajte si pozorne písomnú informáciu pre používateľa. Uchovávať mimo dohľadu a dosahu detí. Výdej lieku je viazaný na lekársky predpis. Nepoužiteľný liek vráťte do lekárne.</p> <p>Registračné číslo: 48/0389/16-S</p> <p>Držiteľ rozhodnutia o registrácii: Guerbet BP 57400, 95943 Roissy CdG Cedex, Francúzsko</p> <p>Č. série: Guerbet</p> <p>Čas použiteľnosti do: L1332SK-B1010-0716 O3010100SK</p>	<p>Optiray® 300 injekčný roztok Léčivo: Ioversolum • Neiónová rtg. kontrastná látka. 100 ml</p> <p>1 ml obsahuje Ioversolum 636 mg (zodpovedá 300 mg jódu/ml). Pomocné látky: trometamol, trometamoliumchlorid, edetát sodno-vápenatý, voda na injekcie. Na intravaskulárnu injekciu alebo infúziu. Uchovávať vnútorný obal v škatuľke. Chrániť pred RTG žiarením. Uchovávať pri teplote do 30°C. Nezmrazovať. Prečítajte si pozorne písomnú informáciu pre používateľa. Uchovávať mimo dohľadu a dosahu detí. Výdej lieku je viazaný na lekársky predpis. Nepoužiteľný liek vráťte do lekárne. Registračné číslo: 48/0389/16-S</p> <p>Držiteľ rozhodnutia o registrácii: Guerbet BP 57400, 95943 Roissy CdG Cedex, Francúzsko</p> <p>L1332-100SK-0218</p> <p>Guerbet</p> <p>Č. série: Čas použiteľnosti do:</p>	