

**HIGHLIGHTS OF PRESCRIBING INFORMATION**

These highlights do not include all the information needed to use OPTIRAY safely and effectively. See full prescribing information for OPTIRAY.

OPTIRAY® (ioversol) injection, for intra-arterial or intra-venous use  
Initial U.S. Approval: 1988

**WARNING: RISKS WITH INADVERTENT INTRATHECAL ADMINISTRATION**

**FOR INTRA-ARTERIAL AND INTRAVENOUS USE ONLY**  
Inadvertent intrathecal administration may cause death, convulsions, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, seizures, rhabdomyolysis, hyperthermia, and brain edema. (5.1)

----- **RECENT MAJOR CHANGES** -----  
Warnings and Precautions (5.8) 2/2022

----- **INDICATIONS AND USAGE** -----

OPTIRAY is a radiographic contrast agent indicated for the following:  
Intra-arterial Procedures (1.1)

Adults:

- Cerebral Arteriography (300, 320 mg iodine/mL)
- Peripheral Arteriography (300, 320, 350 mg iodine/mL)
- Visceral and Renal Arteriography, Aortography (320 mg iodine/mL)
- Coronary Arteriography and Left Ventriculography (320, 350 mg iodine/mL)

Pediatric Patients: Angiocardiology (320, 350 mg iodine/mL)

Intravenous Procedures (1.2)

Adults:

- Computed tomography (CT) Imaging of Head and Body (300, 320, 350 mg iodine/mL)
- Venography (300, 320, 350 mg iodine/mL)
- Intravenous Excretory Urography (300, 320, 350 mg iodine/mL)
- Intravenous Digital Subtraction Angiography (350 mg iodine/mL)

Pediatric Patients: CT Imaging of the Head and Body, and Intravenous Excretory Urography (320 mg iodine/mL)

----- **DOSAGE AND ADMINISTRATION** -----

Adjust the volume and concentration of OPTIRAY. Modify the dose accounting for factors such as age, body weight, vessel size, blood flow rate within the vessel. Please see details in full Prescribing Information. (2)

----- **DOSAGE FORMS AND STRENGTHS** -----

OPTIRAY (ioversol) Injection comes in three strengths: 300 mg iodine/mL (ioversol 64%), 320 mg iodine/mL (ioversol 68%), 350 mg iodine/mL (ioversol 74%) in single-dose vials, bottles, or syringes. (3)

----- **CONTRAINDICATIONS** -----

Symptomatic Hyperthyroidism (4)

----- **WARNINGS AND PRECAUTIONS** -----

- Hypersensitivity Reactions: life-threatening or fatal reactions can occur. Always have emergency equipment and trained personnel available. (5.2)
- Contrast Induced Acute Kidney Injury: Acute injury, including renal failure, can occur. Minimize dose and maintain adequate hydration to minimize risk. (5.3)
- Cardiovascular Adverse Reactions: hemodynamic disturbances including shock and cardiac arrest may occur during or after administration. (5.4)
- Thyroid Dysfunction in Pediatric Patients 0 to 3 Years of Age: Monitor these patients for thyroid function abnormalities and treat as clinically needed. (5.8)

----- **ADVERSE REACTIONS** -----

The most common reaction is nausea, occurring at a rate of 1 percent. (6.1)

To report **SUSPECTED ADVERSE REACTIONS**, contact **LIEBEL-FLARSHEIM COMPANY LLC at 855-266-5037 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

----- **USE IN SPECIFIC POPULATIONS** -----

- Lactation: A lactating woman may pump and discard breast milk for 8 hours after OPTIRAY administration. (8.2)

See 17 for **PATIENT COUNSELING INFORMATION**.

Revised: 5/2022

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## FULL PRESCRIBING INFORMATION

### **WARNING: RISKS WITH INADVERTENT INTRATHECAL ADMINISTRATION**

#### **FOR INTRA-ARTERIAL AND INTRAVENOUS USE ONLY.**

**Inadvertent intrathecal administration may cause death, convulsions, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, seizures, rhabdomyolysis, hyperthermia, and brain edema. [see Warnings and Precautions (5.1)]**

## 1 INDICATIONS AND USAGE

OPTIRAY is indicated for:

### 1.1 Intra-arterial

In adults

- OPTIRAY 300: cerebral arteriography and peripheral arteriography.
- OPTIRAY 320: cerebral arteriography, peripheral arteriography, visceral and renal arteriography, aortography, coronary arteriography, and left ventriculography.
- OPTIRAY 350: peripheral arteriography coronary arteriography, and left ventriculography.

In pediatric patients

- OPTIRAY 320 and OPTIRAY 350: angiocardiology.

### 1.2 Intra-venous

In adults

- OPTIRAY 300: CT imaging of the head and body, venography, and intravenous excretory urography.
- OPTIRAY 320: CT imaging of the head and body, venography, and intravenous excretory urography.
- OPTIRAY 350: CT imaging of the head and body, venography, intravenous excretory urography, and intravenous digital subtraction angiography (IV-DSA).
- In pediatric patients OPTIRAY 320: CT imaging of the head and body, and intravenous excretory urography.

## 2 DOSAGE AND ADMINISTRATION

### 2.1 Important Administration Instructions

- OPTIRAY is for intravascular use only [see *Boxed Warning, Contraindications (4), and Warnings and Precautions (5.1)*].
- Use sterile technique for all handling and administration of OPTIRAY.
- Inspect glass and plastic containers prior to use for breakage or other damage and do not use damaged containers.
- Warm OPTIRAY and administer at body or room temperature.

- Inspect OPTIRAY for particulate matter or discoloration before administration. Do not administer if OPTIRAY contains particulate matter or is discolored.
- Do not mix OPTIRAY with other drugs, solutions or total parenteral nutrition mixtures.
- Use the lowest dose necessary to obtain adequate visualization.
- Adjust the volume and concentration of OPTIRAY. Modify the dose accounting for factors such as age, body weight, vessel size, blood flow rate within the vessel, anticipated pathology, degree and extent of opacification required, structure(s) or area to be examined, disease processes affecting the patient, and equipment and technique to be employed.
- Avoid extravasation when injecting OPTIRAY; especially in patients with severe arterial or venous disease [see *Warnings and Precautions (5.6)*].
- Hydrate patients before and after OPTIRAY administration [see *Warnings and Precautions (5.3)*]
- Discard unused portion of OPTIRAY from single-dose container after use.

## 2.2 Radio Frequency Identification (RFID)-Tagged Syringe Directions for Use

- The RFID-tagged syringe must be used with an Optivantage Injector with RFID technology [see *How Supplied/Storage and Handling (16.2)*]. The RFID tag allows for the exchange of product information such as lot number, expiration, concentration, and identification of the syringe as being “unused” prior to use and “used” after product administration.
- Do not operate any part of the Optivantage Injector System and RFID-tagged syringes within 6 inches (15 cm) of a pacemaker and/or defibrillator.
- If the RFID tag is damaged or otherwise non-functional, the OPTIRAY syringe with the non-functional RFID tag may still be used; however, no data will be transferred to the injector.

## 2.3 Intra-arterial Procedures in Adults

### • Cerebral Arteriography

Use OPTIRAY 300 or OPTIRAY 320. The recommended dose for visualization of cerebral arteries is shown below (may repeat as necessary):

Diagnostic area	Dose	Maximum Cumulative Dose
carotid or vertebral arteries	2 mL to 12 mL	200 mL
aortic arch injection (four vessel study)	20 mL to 50 mL	200 mL

### • Peripheral Arteriography

Use OPTIRAY 300, OPTIRAY 320 or OPTIRAY 350. The recommended dose for visualization of peripheral arteries is shown below (may repeat as necessary):

Diagnostic area	Dose	Maximum Cumulative Dose
aorta-iliac runoff	60 mL (range 20 mL to 90 mL)	250 mL
common iliac, femoral	40 mL (range 10 mL to 50 mL)	250 mL
subclavian, brachial	20 mL (range 15 mL to 30 mL)	250 mL

### • Visceral and Renal Arteriography and Aortography

Use OPTIRAY 320. The recommended dose for visualization for the aorta and visceral arteries is shown below (may repeat as necessary):

Diagnostic area	Dose	Maximum Cumulative Dose
Aorta	45 mL (range 10 mL to 80 mL)	250 mL

Celiac	45 mL (range 12 mL to 60 mL)	250 mL
superior mesenteric	45 mL (range 15 mL to 60 mL)	250 mL
renal or inferior mesenteric	9 mL (range 6 mL to 15 mL)	250 mL

- **Coronary Arteriography and Left Ventriculography**

Use OPTIRAY 320 or OPTIRAY 350. The recommended dose for visualization of the coronary arteries and left ventricle is shown below (may repeat as necessary):

Diagnostic area	Dose	Maximum Cumulative Dose
left coronary	8 mL (range 2 mL to 10 mL)	250 mL
right coronary	6 mL (range 1 mL to 10 mL)	250 mL
left ventricle	40 mL (range 30 mL to 50 mL)	250 mL

## 2.4 Intravenous Procedures in Adults

- **Computed Tomography**

Use OPTIRAY 300, OPTIRAY 320 or OPTIRAY 350 for head and body imaging.

### Head Imaging

The recommended dosing is shown below:

- Scan immediately after completion of the intravenous administration.

	<b>Infusion</b>
OPTIRAY 300	50 mL to 150 mL
OPTIRAY 320	50 mL to 150 mL
OPTIRAY 350	50 mL to 150 mL

### Body Imaging

OPTIRAY may be administered by bolus injection, by rapid infusion, or by a combination of both. The recommended dosing is shown below:

- Scanning interval will vary with indication and target organ.

	<b>Bolus Injection</b>	<b>Infusion</b>
OPTIRAY 300	25 mL to 75 mL	50 mL to 150 mL
OPTIRAY 320	25 mL to 75 mL	50 mL to 150 mL
OPTIRAY 350	25 mL to 75 mL	50 mL to 150 mL

- **Venography**

Use OPTIRAY 300, OPTIRAY 320 or OPTIRAY 350. The recommended dose is 50 mL to 100 mL per extremity; with a maximum cumulative dose of 250 mL.

- **Intravenous Urography**

Use OPTIRAY 350, OPTIRAY 320, or OPTIRAY 300. The recommended dose is shown below:

	<b>Usual Dose</b>	<b>High Dose Urography</b>	<b>Maximum Dose</b>
OPTIRAY 300	50 mL to 75 mL	1.6 mL/kg	150 mL
OPTIRAY 320	50 mL to 75 mL	1.5 mL/kg to 2 mL/kg	150 mL
OPTIRAY 350	50 mL to 75 mL	1.4 mL/kg	140 mL

- **Intravenous Digital Subtraction Angiography (IV-DSA)**

Use OPTIRAY 350. The recommended dose range per injection is 30 mL to 50 mL; may repeat as necessary with a maximum cumulative dose of 250mL.

Injection rates will vary depending on the site of catheter placement and vessel size.

- Central catheter injections are usually made at a rate of between 10 mL/second and 30 mL/second.
- Peripheral injections are usually made at a rate of between 12 mL/second and 20 mL/second.

## 2.5 Pediatric Dosing

### Intra-arterial Procedures

- **Angiocardiology**

Use OPTIRAY 350 or OPTIRAY 320. The recommended single ventricular dose is 1.25 mL/kg (range 1 mL/kg to 1.5 mL/kg). The maximum cumulative dose is 5 mL/kg up to a maximum total volume of 250 mL.

### Intravenous Procedures

- **Computed Tomography**

Use OPTIRAY 320.

#### Head and Body Imaging

The recommended dose in pediatric patients is 1.5 mL/kg to 2 mL/kg (range 1 mL/kg to 3 mL/kg).

- **Intravenous Urography**

Use OPTIRAY 320. The recommended dose for pediatric patients is 1 mL/kg to 1.5 mL/kg (range 0.5 mL/kg to 3 mL/kg); with a maximum cumulative dose not exceeding 3 mL/kg.

## 3 DOSAGE FORMS AND STRENGTHS

Injection: clear, colorless to pale yellow solutions containing no undissolved solids, available in the following strengths and single-dose containers:

Imaging Product	mg of ioversol per mL	mg of organically bound iodine per mL	Presentations			
			Vials	Bottles	Hand-held syringes	Power injector syringes
OPTIRAY 300 (loversol 64%)	636	300	No	Yes	Yes	Yes
OPTIRAY 320 (loversol 68%)	678	320	Yes	Yes	Yes	Yes
OPTIRAY 350 (loversol 74%)	741	350	No	Yes	Yes	Yes

## 4 CONTRAINDICATIONS

Symptomatic hyperthyroidism.

## 5 WARNINGS AND PRECAUTIONS

### 5.1 Risks Associated with Inadvertent Intrathecal Administration

OPTIRAY is indicated for intravascular use only [see *Dosage and Administration (2.1)*]. Inadvertent intrathecal administration can cause death, convulsions, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, seizures, rhabdomyolysis, hyperthermia, and brain edema.

### 5.2 Hypersensitivity Reactions

OPTIRAY can cause life-threatening or fatal hypersensitivity reactions including anaphylaxis and anaphylactic shock. Manifestations include respiratory arrest, laryngospasm, bronchospasm, angioedema, and shock. Most severe reactions develop shortly after the start of the injection (e.g. within 1 to 3 minutes), but delayed reactions may occur. There is an increased risk in patients with a history of a previous reaction to contrast agent, and known allergies (i.e., bronchial asthma, drug, or food allergies), and other hypersensitivities. Premedication with antihistamines or corticosteroids to avoid or minimize possible allergic reactions does not prevent serious life-threatening reactions, but may reduce both their incidence and severity.

Obtain a history of allergy, hypersensitivity, or prior hypersensitivity reactions to iodinated contrast agents. Always have emergency resuscitation equipment and trained personnel available and monitor all patients for hypersensitivity reactions.

### 5.3 Contrast Induced Acute Kidney Injury

Acute kidney injury, including renal failure, may occur after OPTIRAY administration. Risk factors include: pre-existing renal impairment, dehydration, diabetes mellitus, congestive heart failure, advanced vascular disease, elderly age, concomitant use of nephrotoxic or diuretic medications, multiple myeloma / paraproteinaceous diseases, repetitive and/or large doses of an iodinated contrast agent.

Use the lowest necessary dose of OPTIRAY in patients with renal impairment. Adequately hydrate patients prior to and following OPTIRAY administration. Do not use laxatives, diuretics, or preparatory dehydration prior to OPTIRAY administration.

### 5.4 Cardiovascular Adverse Reactions

OPTIRAY increases the circulatory osmotic load and may induce acute or delayed hemodynamic disturbances in patients with congestive heart failure, severely impaired renal function, combined renal and hepatic disease, combined renal and cardiac disease, particularly when repetitive or large doses are administered.

Life-threatening or fatal cardiovascular reactions have occurred with the use of OPTIRAY, including cardiac arrest, hypotensive collapse, and shock. Most deaths occur within 10 minutes of injection; with cardiovascular disease as the main underlying factor. Cardiac decompensation, serious arrhythmias, and myocardial ischemia or infarction can occur during coronary arteriography and ventriculography.

Based upon literature reports, deaths from the administration of iodinated contrast agents range from 6.6 per 1 million (0.00066 percent) to 1 in 10,000 patients (0.01 percent). Use the lowest necessary dose of OPTIRAY in patients with congestive heart failure and always have emergency resuscitation equipment and trained personnel available. Monitor all patients for severe cardiovascular reactions.

### 5.5 Thromboembolic Events

#### Angiocardiology

Serious, fatal, thromboembolic events causing myocardial infarction and stroke can occur during angiographic procedures with OPTIRAY. During these procedures, increased thrombosis and activation of the complement system occurs. Risk factors for thromboembolic events include: length of procedure, catheter and syringe material, underlying disease state, and concomitant medications.

To minimize thromboembolic events use meticulous angiographic technique. Avoid blood remaining in contact with syringes containing OPTIRAY, which increases the risk of clotting. Avoid angiocardiology in patients with homocystinuria because of the risk of inducing thrombosis and embolism [see *Clinical Pharmacology (12.2)*].

### **5.6 Extravasation and Injection Site Reactions**

Extravasation can occur with OPTIRAY administration, particularly in patients with severe arterial or venous disease and can be associated with pain, hemorrhage and necrosis. Ensure intravascular placement of catheters prior to injection. Monitor patients for extravasation and advise patients to seek medical care for progression of symptoms.

### **5.7 Thyroid Storm in Patients with Hyperthyroidism**

OPTIRAY is contraindicated in patients with symptomatic hyperthyroidism [see *Contraindications (4)*]. Thyroid storm has occurred following the intravascular use of iodinated radiopaque agents in patients with hyperthyroidism or with an autonomously functioning thyroid nodule. Evaluate the risk in such patients before use of OPTIRAY.

### **5.8 Thyroid Dysfunction in Pediatric Patients 0 to 3 Years of Age**

Thyroid dysfunction characterized by hypothyroidism or transient thyroid suppression has been reported after both single exposure and multiple exposures to iodinated contrast media. Among patients 0 to 3 years of age exposed to iodinated contrast media, thyroid dysfunction has been reported in 1% to 15% depending on the age of the patient and the dose of the iodinated contrast agent.

Younger age, very low birth weight, prematurity, and the presence of other conditions, such as, admission to neonatal or pediatric intensive care units, and cardiac conditions are associated with an increased risk. Pediatric patients with cardiac conditions may be at the greatest risk given that they often require high doses of contrast during invasive cardiac procedures, such as catheterization and computed tomography (CT).

Pediatric patients 0 to 3 years of age warrant closer monitoring because an underactive thyroid during early life may be harmful for motor, hearing, and cognitive development and may require transient T4 replacement therapy. Evaluate thyroid function in all pediatric patients 0 to 3 years of age within 3 weeks following exposure to iodinated contrast media, especially in term and preterm neonates. If thyroid dysfunction is detected, treat and monitor thyroid function as clinically needed.

### **5.9 Hypertensive Crisis in Patients with Pheochromocytoma**

Hypertensive crisis has occurred after the use of iodinated radiopaque contrast agents in patient with pheochromocytoma. Closely monitor patients when administering OPTIRAY if pheochromocytoma or catecholamine-secreting paraganglioma is suspected. Inject the minimum amount of OPTIRAY necessary and have measures for treatment of hypertensive crisis readily available.

### **5.10 Sickle Cell Crisis in Patients with Sickle Cell Disease**

Iodinated contrast agents may promote sickling in individuals who are homozygous for sickle cell disease. Hydrate patients prior to and following OPTIRAY administration, use OPTIRAY only if the

necessary imaging information cannot be obtained with alternative imaging modalities, and inject the minimum amount necessary.

### 5.11 Severe Cutaneous Adverse Reactions

Severe cutaneous adverse reactions (SCAR) may develop from 1 hour to several weeks after intravascular contrast agent administration. These reactions include Stevens-Johnson syndrome and toxic epidermal necrolysis (SJS/TEN), acute generalized exanthematous pustulosis (AGEP) and drug reaction with eosinophilia and systemic symptoms (DRESS). Reaction severity may increase and time to onset may decrease with repeat administration of a contrast agent; prophylactic medications may not prevent or mitigate severe cutaneous adverse reactions. Avoid administering OPTIRAY to patients with a history of a severe cutaneous adverse reaction to OPTIRAY.

## 6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Risks Associated with Inadvertent Intrathecal Administration [*see Warnings and Precautions (5.1)*]
- Hypersensitivity Reactions [*see Warnings and Precautions (5.2)*]
- Contrast Induced Acute Kidney Injury [*see Warnings and Precautions (5.3)*]
- Cardiovascular Adverse Reactions [*see Warnings and Precautions (5.4)*]
- Thromboembolic Events [*see Warnings and Precautions (5.5)*]
- Thyroid Dysfunction Pediatric Patients 0 to 3 Years of Age [*see Warnings and Precautions (5.8)*]
- Severe Cutaneous Adverse Reactions [*see Warnings and Precautions (5.11)*]

### 6.1 Clinical Trials Experience

#### Adult Patients

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The following listing shows adverse reactions based upon clinical trials with OPTIRAY (ioversol) in 4,187 patients. Adverse reactions are listed by organ system according to clinical importance. More severe reactions are listed before others in a system regardless of incidence. The most common reaction is nausea, occurring at a rate of 1 percent.

#### *Cardiac disorders*

Cardiac arrest, myocardial infarction, arrhythmia, atrioventricular block complete, atrioventricular block, nodal rhythm, bradycardia, angina pectoris, palpitations

#### *Ear and labyrinth disorders*

Vertigo, tinnitus

#### *Eye disorders*

Vision blurred, periorbital edema, conjunctivitis

#### *Gastrointestinal disorders*

Nausea, vomiting, abdominal pain, dysphagia, dry mouth

#### *General disorders and administration site conditions*

Chest pain, pain, injection site pain, injection site hematoma, extravasation, pyrexia, swelling, asthenia, malaise, fatigue, chills

#### *Infections and infestations*

Rhinitis

*Injury, poisoning, and procedural complications*

Heart injury, vascular pseudoaneurysm

*Investigations*

Electrocardiogram ST segment depression, blood pressure decreased

*Metabolism and nutrition disorders*

Acidosis

*Musculoskeletal and connective tissue disorders*

Muscular weakness, muscle spasms, back pain

*Nervous system disorders*

Cerebral infarction, aphasia, tremor, dizziness, presyncope, headache, paraesthesia, dysgeusia

*Psychiatric disorders*

Hallucination, visual hallucination, disorientation, anxiety

*Renal and urinary disorders*

Urinary retention, renal pain, polyuria

*Respiratory, thoracic, and mediastinal disorders*

Laryngeal edema, hypoxia, pulmonary edema, dyspnea, hyperventilation, cough, sneezing, nasal congestion

*Skin and subcutaneous tissue disorders*

Urticaria, rash, pruritus, swelling face, hyperhidrosis, erythema

*Vascular disorders*

Hypertension, hypotension, arterial spasm, vasospasm, vasodilation, flushing

Pediatric Patients

In clinical studies involving 311 patients for pediatric angiocardiology, contrast enhanced computed tomographic imaging of the head and body, and intravenous excretory urography; 6% of patients reported an adverse reaction, with the most common adverse reactions being nausea and fever. Adverse reactions reported were similar in quality and frequency to the adverse events reported by adults.

**6.2 Postmarketing Experience**

The following additional adverse drug reactions have been reported during post-approval use of OPTIRAY. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate frequency [or establish a causal relationship to drug exposure](#).

*Cardiac disorders:* coronary artery spasm, cyanosis, arrhythmia (ventricular fibrillation, tachycardia, extrasystole), ECG abnormal.

*Endocrine disorders* Hyperthyroidism, hypothyroidism.

*Eye disorders:* temporary blindness, conjunctivitis (including eye irritation, ocular hyperemia, watery eyes).

*Gastrointestinal disorders:* tongue edema, salivary hypersecretion.

*General disorders and administration site conditions:* injection site reactions including pain, hemorrhage, and necrosis especially after extravasation [see *Warnings and Precautions (5.6)*], face edema, feeling hot.

*Immune system disorders:* hypersensitivity reactions including fatal anaphylactic shock.

*Nervous system disorders:* seizure, loss of consciousness, somnolence, hypoesthesia, dyskinesia, amnesia.

*Respiratory disorders:* Respiratory arrest, asthma, bronchospasm, laryngeal spasm and obstruction, throat irritation, dysphonia.

*Skin and subcutaneous tissue disorders:* Reactions range from mild (e.g. rash, erythema, pruritus, urticaria, and skin discoloration) to severe: [e.g. Stevens-Johnson syndrome and toxic epidermal necrolysis (SJS/TEN)], acute generalized exanthematous pustulosis (AGEP) and drug reaction with eosinophilia and systemic symptoms (DRESS).

*Vascular Disorders:* phlebitis, thrombosis.

## **7 DRUG INTERACTIONS**

### **7.1 Drug-Drug Interactions**

#### Metformin

In patients with renal impairment, metformin can cause lactic acidosis. Iodinated contrast agents appear to increase the risk of metformin induced lactic acidosis, possibly as a result of worsening renal function. Stop metformin at the time of, or prior to, OPTIRAY administration in patients with an eGFR between 30 and 60 mL/min/1.73 m<sup>2</sup>; in patients with a history of hepatic impairment, alcoholism or heart failure; or in patients who will be administered intra-arterial iodinated contrast agents. Re-evaluate eGFR 48 hours after the imaging procedure, and reinstitute only after renal function is stable.

#### Radioactive Iodine

Administration of iodinated contrast agents may interfere with thyroid uptake of radioactive iodine (I-131) and decrease therapeutic efficacy in patients with carcinoma of the thyroid. The decrease in efficacy lasts for 6-8 weeks.

#### Oral Cholecystographic Contrast Agents

Renal toxicity has been reported in patients with liver impairment who were given oral cholecystographic agents followed by intravascular contrast agents. Administration of OPTIRAY should be postponed in patients who have recently received a cholecystographic contrast agent.

### **7.2 Drug/Laboratory Test Interactions**

#### Protein-Bound Iodine, Radioactive Iodine Determinations

The results of 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 contrast agent. However, thyroid function tests that do not depend on iodine estimations, e.g., T3 resin uptake and total or free thyroxine (T4) assays are not affected.

## **8 USE IN SPECIFIC POPULATIONS**

### **8.1 Pregnancy**

#### Risk Summary

Postmarketing data with OPTIRAY use in pregnant women are insufficient to determine if there is a risk of drug-associated adverse developmental outcomes. Ioversol crosses the placenta and reaches fetal tissues in small amounts [see Data]. In animal reproduction studies, no adverse developmental effects were observed following daily intravenous administrations of ioversol to pregnant rats (from Gestation Day 7 to 17) and rabbits (Gestation Day 6 to 18) at doses 0.35 and 0.71 times, respectively, the maximum recommended human dose.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of major birth defects, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriages in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

## Data

### *Human Data*

Literature reports show that ioversol crosses the placenta and is visualized in the digestive tract of exposed infants after birth.

### *Animal Data*

Developmental toxicity studies were conducted with ioversol given intravenously at doses of 0, 0.2, 0.8, and 3.2 g iodine/kg/day from Gestation Day 7 to 17 and 6 to 18, in rats and rabbits, respectively. No adverse effects on embryo-fetal development were observed in either species at the maximum dose tested (3.2 g iodine/kg/day). Maternal toxicity was observed in rabbits at 0.8 and 3.2 g iodine/kg/day.

## **8.2 Lactation**

### Risk Summary

There is no information about the presence of ioversol in human or animal milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production. However, iodinated contrast agents are excreted unchanged in human milk in very low amounts with poor absorption from the gastrointestinal tract of the breastfed infant. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for OPTIRAY and any potential adverse effects on the breastfed infant from OPTIRAY or from the underlying maternal condition.

### Clinical Considerations

Interruption of breastfeeding after exposure to iodinated contrast agents is not necessary because the potential exposure of the breastfed infant to iodine is small. However, a lactating woman may consider interrupting breastfeeding and pumping and discarding breast milk for 8 hours (approximately 5 elimination half-lives) after OPTIRAY administration in order to minimize drug exposure to a breastfed infant.

## **8.4 Pediatric Use**

Safety and effectiveness in pediatric patients have been established for the use of OPTIRAY 350 and OPTIRAY 320 in angiocardiology; and for OPTIRAY 320 in computed tomographic imaging of the head and body, and intravenous excretory urography. Use of OPTIRAY 350 and OPTIRAY 320 in these age groups is based on controlled clinical trials involving 159 patients for pediatric angiocardiology; computed tomographic imaging of the head and body, and intravenous excretory urography. In general, the types of adverse reactions reported are similar to those of adults [see Adverse Reactions (6.1)].

Safety and effectiveness of OPTIRAY 300 has not been established in pediatric patients.

Pediatric patients at higher risk of experiencing adverse reactions to OPTIRAY include patients with: asthma, sensitivity to medication and/or allergens, congestive heart failure, serum creatinine greater than 1.5 mg/dL, or age less than 12 months.

Thyroid function tests indicative of thyroid dysfunction, characterized by hypothyroidism or transient thyroid suppression have been uncommonly reported following iodinated contrast media administration in pediatric patients, including term and preterm neonates; some patients were treated

for hypothyroidism. Monitor pediatric patients 0 to 3 years of age closely, particularly those with one or more potential risk factors, for thyroid dysfunction [see *Warnings and Precautions (5.8) and Adverse Reactions (6.2)*].

### 8.5 Geriatric Use

Ioversol is nearly completely excreted as parent drug by the kidney, and the risk of adverse reactions to OPTIRAY may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, dose selection should be cautious usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

### 8.6 Renal Impairment

Ioversol is nearly completely excreted as parent drug by the kidney and renal impairment is expected to reduce the rate of elimination. Ioversol can be removed by dialysis.

## 10 OVERDOSAGE

The adverse effects of overdosage are life-threatening and affect mainly the pulmonary and cardiovascular system. Treatment of an overdosage is directed toward the support of all vital functions and prompt institution of symptomatic therapy.

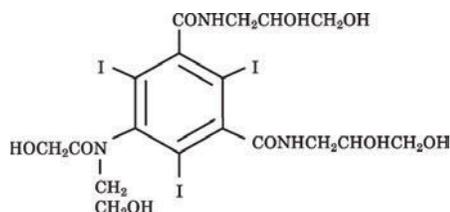
Ioversol does not bind to plasma or serum protein and is, therefore, dialyzable.

## 11 DESCRIPTION

### 11.1 Chemical Characteristics

OPTIRAY (ioversol injection) is a non-ionic radiographic contrast agent. OPTIRAY formulations are sterile, nonpyrogenic, aqueous solutions intended for intravascular use. Ioversol is designated chemically as *N,N'*-Bis (2,3-dihydroxypropyl)-5-[*N*-(2-hydroxyethyl) -glycolamido] -2,4,6-triiodoisophthalamide. The molecular weight of ioversol is 807.11 and the organically bound iodine content is 47.2%.

The structural formula of ioversol is as follows:



OPTIRAY is available in three strengths:

- **OPTIRAY 300** (ioversol injection 64%): Each mL contains 300 mg organically bound iodine, 636 mg ioversol, 3.6 mg tromethamine, 0.2 mg edetate calcium disodium.
- **OPTIRAY 320** (ioversol injection 68%): Each mL contains 320 mg organically bound iodine, 678 mg of ioversol, 3.6 mg tromethamine, 0.2 mg edetate calcium disodium.
- **OPTIRAY 350** (ioversol injection 74%): Each mL contains 350 mg organically bound iodine, 741 mg ioversol, 3.6 mg tromethamine, 0.2 mg edetate calcium disodium.

The pH of the OPTIRAY formulations is adjusted to 6.0 to 7.4 with hydrochloric acid or sodium hydroxide. All solutions are sterilized by autoclaving and contain no preservatives. Ioversol does not dissociate in solution.

## 11.2 Physical Characteristics

Some physical and chemical properties of these formulations are listed below:

	OPTIRAY 300	OPTIRAY 320	OPTIRAY 350
Ioversol content (mg/mL)	636	678	741
Iodine content (mg I/mL)	300	320	350
Osmolality (mOsm/kg water)	651	702	792
Viscosity (cps) at 25°C	8.2	9.9	14.3
at 37°C	5.5	5.8	9.0
Specific Gravity at 37°C	1.352	1.371	1.405

The OPTIRAY formulations are clear, colorless to pale yellow solutions containing no undissolved solids. Crystallization does not occur at room temperature. OPTIRAY solutions have osmolalities 1.8 to 2.8 times that of plasma (285 mOsm/kg water) as shown in the above table and are hypertonic under conditions of use.

## 12 CLINICAL PHARMACOLOGY

### 12.1 Mechanism of Action

Intravascular injection of ioversol opacifies vessels in the path of the flow of the contrast medium, permitting visualization of the internal structures until significant hemodilution occurs.

In imaging of the body, iodinated contrast agents diffuse from the vascular into the extravascular space. In normal brain with an intact blood-brain barrier, contrast does not diffuse into the extravascular space. In patients with a disrupted blood-brain barrier, contrast agent accumulates in the interstitial space in the region of disruption.

### 12.2 Pharmacodynamics

Following administration of OPTIRAY, the degree of enhancement is directly related to the iodine content in an administered dose. Peak iodine plasma levels occur immediately following rapid injection. The time to maximum contrast enhancement can vary, depending on the organ, from the time that peak blood iodine concentrations are reached to one hour after intravenous bolus administration. When a delay between peak blood iodine concentrations and peak contrast is present, it suggests that radiographic contrast enhancement is at least in part dependent on the accumulation of iodine-containing medium within the lesion and outside the blood pool.

For angiography, contrast enhancement is greatest immediately (15 seconds to 120 seconds) after rapid injection. Iodinated contrast agents may be visualized in the renal parenchyma within 30-60 seconds following rapid intravenous injection. Opacification of the calyces and pelves in patients with normal renal function becomes apparent within 1-3 minutes, with optimum contrast occurring within 5-15 minutes.

### 12.3 Pharmacokinetics

In 12 healthy volunteers (6 receiving 50 mL and 6 receiving 150 mL of OPTIRAY 320), elimination half-life was 1.5 hours for both doses.

#### Distribution

In an *in vitro* human plasma study, ioversol did not bind to protein. The volume of distribution in adults was 0.26 L/kg body weight, consistent with distribution to the extracellular space.

## Elimination

### Metabolism

Ioversol does not undergo significant metabolism, deiodination or biotransformation.

### Excretion

Greater than 95% of the administered dose was excreted in urine within the first 24 hours, with the peak urine concentration occurring in the first two hours after administration.

## **13 NONCLINICAL TOXICOLOGY**

### **13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility**

No long term animal studies have been performed to evaluate carcinogenic potential. Nonclinical studies show that Ioversol is not mutagenic and does not affect fertility.

### **13.2 Animal Toxicology and/or Pharmacology**

Animal studies indicate that Ioversol does not cross the blood-brain barrier.

## **16 HOW SUPPLIED/STORAGE AND HANDLING**

### **16.1 How Supplied**

OPTIRAY is a clear, colorless to pale yellow, sterile, pyrogen-free, aqueous solution available in three strengths. The products are supplied in containers from which the air has been displaced by nitrogen. OPTIRAY is supplied in the following single-dose configurations:

#### **OPTIRAY 350**

##### Glass

25x50 mL bottles	0019-1333-06
12x100 mL bottles	0019-1333-11
12x150 mL bottles	0019-1333-16
12x200 mL fill/250 mL bottles	0019-1333-21

##### Plastic

20x50 mL hand held syringes	0019-1333-78
20x75 mL fill/125 mL power injector syringes	0019-1333-95
20x100 mL fill/125 mL power injector syringes	0019-1333-90
20x125 mL power injector syringes	0019-1333-87

##### RFID-Tagged Syringes\*

20x100 mL fill/125 mL power injector syringes	0019-1333-00
20x125 mL power injector syringes	0019-1333-27

#### **OPTIRAY 320**

##### Glass

25x20 mL vials	0019-1323-02
25x50 mL bottles	0019-1323-06
12x100 mL bottles	0019-1323-11
12x150 mL bottles	0019-1323-16
12x200 mL fill/250 mL bottles	0019-1323-21

##### Plastic

20x50 mL hand held syringes	0019-1323-78
20x50 mL fill/125 mL power injector syringes	0019-1323-52
20x75 mL fill/125 mL power injector syringes	0019-1323-95
20x100 mL fill/125 mL power injector syringes	0019-1323-90
20x125 mL power injector syringes	0019-1323-87

##### RFID-Tagged Syringes\*

20x75 mL fill/125 mL power injector syringes	0019-1323-85
20x100 mL fill/125 mL power injector syringes	0019-1323-00

20x125 mL power injector syringes

0019-1323-27

## **OPTIRAY 300**

### Glass

25x50 mL bottles

0019-1332-06

12x100 mL bottles

0019-1332-11

12x150 mL bottles

0019-1332-16

12x200 mL fill/250 mL bottles

0019-1332-21

### Plastic

20x100 mL fill/125 mL power injector syringes

0019-1332-90

### RFID-Tagged Syringes\*

20x100 mL fill/125 mL power injector syringes

0019-1332-00

## **\*Radio Frequency Identification (RFID) Technology**

### **RFID-Tagged Syringe Description**

This information is for Ultraject™ syringes containing OPTIRAY that have been labeled with a Radio Frequency Identification (RFID) tag. When used with an RFID-enabled Optivantage™ injector, this tag allows for the exchange of product information such as lot number, expiration, concentration, and identification of the syringe as being “unused” prior to use and “used” after product administrations. Patient information is not used in any form with this RFID technology. OPTIRAY product quality is not influenced by the use of this RFID tag.

### **RFID-Tagged Syringe Directions for Use**

For the RFID Technology to function, the syringe must be used with an Optivantage Injector with RFID technology [see *Dosage and Administration (2.2)*]. Function of the RFID technology is not dependent on syringe orientation as it is placed in the injector. Instructions for use of injector are provided on the injector interface screen and operator’s manual.

If the RFID tag is damaged or otherwise non-functional, the injector will notify the user. Should this occur the OPTIRAY syringe with the non-functional RFID tag may still be used but no data will be transferred to the injector.

Regarding interference with medical devices, the RFID tag and injector system meet the IEC 60601-1-2 requirements for emission and immunity standards for medical devices. Follow all manufacturers’ guidelines and do not operate any part of the Optivantage Injector System and RFID-tagged syringes within 6 inches (15 cm) of a pacemaker and/or defibrillator.

## **16.2 Storage**

- Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F).
- Protect from strong daylight or direct exposure to the sun.
- Store up to 40°C (104°F) for up to one month in a contrast media warmer utilizing circulating warm air.
- May store OPTIRAY for periods longer than one month.
- Store OPTIRAY RFID-tagged syringes at the same conditions listed for the drug product.
- Discard OPTIRAY syringes, glass bottles, and their contents if they are frozen or if crystallization occurs.

## **16.3 Handling**

- Do not re-autoclave plastic container because of possible damage to syringe.
- RFID-tagged syringes require no special handling.

## 17 PATIENT COUNSELING INFORMATION

### Hypersensitivity Reactions

Advise the patient concerning the risk of hypersensitivity reactions that can occur both during and after OPTIRAY administration. Advise the patient to report any signs or symptoms of hypersensitivity reactions during the procedure and to seek medical attention for signs or symptoms experienced after discharge [see *Warnings and Precautions (5.2)*].

Advise patients to inform their physician if they develop a rash after receiving OPTIRAY [see *Warnings and Precautions (5.10)*].

### Contrast Induced Acute Kidney Injury

Advise the patient concerning appropriate hydration to decrease the risk of contrast induced kidney injury [see *Warnings and Precautions (5.3)*].

### Extravasation

If extravasation occurs during injection, advise patients to seek medical care for progression of symptoms [see *Warnings and Precautions (5.6)*].

### Thyroid Dysfunction

Advise parents/caregivers about the risk of developing thyroid dysfunction after OPTIRAY administration. Advise parents/caregivers about when to seek medical care for their child to monitor for thyroid function [see *Warnings and Precautions (5.8)*].

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616

Made in USA



GBT 1323C0422

Single-Dose Container Sterile Solution **Optiray<sup>®</sup> 350** 50 mL NDC 0019-1333-06

Lot: [Redacted]  
Mfg: [Redacted]  
Exp: [Redacted]

**Rx only**  
Not For Intrathecal Use  
Guerbet | 

**Ioversol Injection 74%**  
350 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only**

**Protect from light** • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Discard contents if product is frozen or if crystallization occurs.  
Each mL contains 741 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer.  
The pH is adjusted with hydrochloric acid or sodium hydroxide.  
**Single dose container • Discard unused portion**  
**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

12631021

Manufactured by:  
Liebel-Flanzheim Company LLC  
Raleigh, NC 27616  
Made in USA

**Optiray<sup>®</sup> 350** 50 mL NDC 0019-1333-06  
Single-Dose Container Sterile Solution

**Ioversol Injection 74%**



05	Lot	Single-Dose Container	<b>Optiray<sup>®</sup> 350</b>	100 mL	75
		Sterile Solution		NDC 0019-1333-11	
57	Mfg	<b>Ioversol Injection 74%</b>			50
		350 mg/mL Organically Bound Iodine			
00L	Exp	<b>For Intravenous and Intra-arterial Use Only</b>			25
		<p><b>Protect from light</b> • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Discard contents if product is frozen or if crystallization occurs. Each mL contains 741 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.</p> <p><b>Single dose container • Discard unused portion</b></p> <p><b>Recommended Dosage:</b> See Prescribing Information for indications, dosage and dispensing information.</p>			
<b>Rx only</b> <b>Not For</b> <b>Intrathecal Use</b> <b>Guerbet</b>		<b>Ioversol Injection 74%</b> Single-Dose Container Sterile Solution <b>Optiray<sup>®</sup> 350</b> 100 mL NDC 0019-1333-11			12651021 3 00191333117
Manufactured by: Liebel-Flarsheim Company LLC Raleigh, NC 27616 Made in USA					

125 SZ

100 00L

75 SZL

50 0SL

25

Single-Dose Container  
Sterile Solution

## Optiray® 350

**Ioversol Injection 74%**  
350 mg/mL Organically Bound Iodine

For Intravenous and Intra-arterial Use Only

**Protect from light** • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Discard contents if product is frozen or if crystallization occurs. Each mL contains 741 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.  
**Single dose container • Discard unused portion**  
**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

150 mL

NDC 0019-1333-16

Lot: [REDACTED]

Mfg: [REDACTED]

Exp: [REDACTED]

**Rx only**  
Not For  
Intrathecal Use

**Guerbet** |

150 mL

NDC 0019-1333-16

3 0 0 1 9 1 3 3 3 1 6 2

001  
125  
051  
175  
200

Single-Dose Container  
Sterile Solution

# Optiray<sup>®</sup> 350

**loversol Injection 74%**  
350 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only**

**Rx only  
Not For  
Intrathecal Use**

**Protect from light** • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Discard contents if product is frozen or if crystallization occurs.  
Each mL contains 741 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Single dose container • Discard unused portion**  
**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

200 mL  
NDC 0019-1333-21



**Guerbet** | 

12671021

Single-Dose Container  
Sterile Solution

NDC 0019-1333-21

200 mL

**Optiray<sup>®</sup> 350**

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616  
Made in USA



(b) (4)

# Optiray® 350

Single-Dose Container  
Sterile Solution

1333BOT

**Ioversol Injection 74%**  
350 mg/mL Organically Bound Iodine

**For Intravenous and  
Intra-arterial Use Only**

Not For Intrathecal Use  
**Rx only**

33USB90L0422

25 x 50 mL bottles

SKU: 133306

EXP: MM/YYYY

LOT: P P P P P P P P

QTY: 25

MFG: MM/YYYY

Linear Barcode

(17)YYMMDD(10)PPPPPPPP(30)XX(11)YYMMDD

NDC 0019-1333-06

GTIN-14 Barcode

**Protect from light** - Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].  
Discard contents if product is frozen or if crystallization occurs.

**Single dose containers - Discard unused portion**  
Each mL contains 741 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer.  
The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Liebel-Fleisher Company LLC  
Raleigh, NC 27616  
Made in USA

**Guerbet** |



(b) (4)

# Optiray® 350

**Ioversol Injection 74%**  
350 mg/mL Organically Bound Iodine

**For Intravenous and  
Intra-arterial Use Only**

Not For Intrathecal Use  
**Rx only**

33USB90L0422

Single-Dose Container  
Sterile Solution

1333BOT

**Protect from light** - Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].  
Discard contents if product is frozen or if crystallization occurs.

**Single dose containers - Discard unused portion**

Each mL contains 741 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer.  
The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Lieber-Farshem Company LLC  
Raleigh, NC 27616  
Made in USA

**Guerbet** |

12 x 100 mL bottles

SKU: 133311

EXP: MM/YYYY    LOT: P P P P P P P P    QTY: 12    MFG: MM/YYYY

Linear Barcode

(17)YYMMDD(10)PPPPPPPP(30)XX(11)YYMMDD

NDC 0019-1333-11

GTIN-14 Barcode



(b) (4)

# Optiray® 350

**Ioversol Injection 74%**  
350 mg/mL Organically Bound Iodine

**For Intravenous and  
Intra-arterial Use Only**

Not For Intrathecal Use  
**Rx only**

33USB90L0422

Single-Dose Container  
Sterile Solution

1333BOT

**Protect from light** - Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].  
Discard contents if product is frozen or if crystallization occurs.

**Single dose containers - Discard unused portion**  
Each mL contains 741 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer.  
The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Lieber-Farshem Company LLC  
Raleigh, NC 27616  
Made in USA

**Guerbet** |

12 x 150 mL bottles

SKU: 133316

EXP: MM/YYYY LOT: P P P P P P P P P P QTY: 12 MFG: MM/YYYY

Linear Barcode

(17)YYMMDD(10)PPPPPPPP(30)XX(11)YYMMDD

NDC 0019-1333-16

GTIN-14 Barcode

(b) (4)

# Optiray® 350

Single-Dose Container  
Sterile Solution

1333BOT

**Ioversol Injection 74%**  
350 mg/mL Organically Bound Iodine

**For Intravenous and  
Intra-arterial Use Only**

Not For Intrathecal Use  
**Rx only**

12 x 200 mL bottles

SKU: 133321

EXP: MM/YYYY    LOT: P P P P P P P P    QTY: 12    MFG: MM/YYYY

Linear Barcode

(17)YYMMDD(10)PPPPPPPP(30)XX(11)YYMMDD

NDC 0019-1333-21

GTIN-14 Barcode

**Protect from light** - Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Discard contents if product is frozen or if crystallization occurs.

**Single dose containers - Discard unused portion**  
Each mL contains 741 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Lieber-Farshem Company LLC  
Raleigh, NC 27616  
Made in USA

**Guerbet** | 

33USB90L0422



Single Dose Container  
Sterile Solution

# Optiray<sup>®</sup> 350

50 mL  
NDC 0019-1333-78

**Ioversol Injection 74%**  
350 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only**

**Rx only**

Not For Intrathecal Use

**Medication and fluid pathway are sterile. Outside of syringe is not sterile.**

**Single dose syringe • Discard unused portion and syringe.**

**Protect from light • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F)** [see USP Controlled Room Temperature].

Each mL contains 741 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616 Made in USA

**Guerbet**



Lot:  
Mfg:  
Exp:



15531021

Single Dose Container 75 mL  
Sterile Solution NDC 0019-1333-95

# Optiray<sup>®</sup> 350

**Ioversol Injection 74%**  
350 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only** **Rx only**

Not For Intrathecal Use

**Medication and fluid pathway are sterile.**  
**Outside of syringe is not sterile.**  
**Single dose syringe • Discard unused portion and syringe.**  
**Protect from light •** Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].  
Each mL contains 741 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide. Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.  
**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616 Made in USA

Lot:   
Mfg:   
Exp:

Guerbet | 

155510.21



3 00191 33395 7

Single Dose Container  
Sterile Solution

100 mL  
NDC 0019-1333-90

# Optiray<sup>®</sup> 350

**Ioversol Injection 74%**  
350 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only**    **Rx only**

Not For Intrathecal Use

**Medication and fluid pathway are sterile. Outside of syringe is not sterile.  
Single dose syringe • Discard unused portion and syringe.**

**Protect from light** • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F)  
[see USP Controlled Room Temperature].

Each mL contains 741 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide. Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616    Made in USA

**Guerbet** | 



Lot:  
Mfg:  
Exp:

15561021

Single Dose Container  
Sterile Solution

125 mL  
NDC 0019-1333-87

# Optiray<sup>®</sup> 350

**Ioversol Injection 74%**  
350 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only**    **Rx only**

Not For Intrathecal Use

**Medication and fluid pathway are sterile. Outside of syringe is not sterile.  
Single dose syringe • Discard unused portion and syringe.**

**Protect from light** • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F)  
[see USP Controlled Room Temperature].

Each mL contains 741 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide. Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616    Made in USA

**Guerbet** | 



Lot:  
Mfg:  
Exp:

15571021

3378CT  
R10/21

**Optiray<sup>®</sup> 350**      Single Dose Container      50 mL  
Sterile Solution      NDC 0019 1333 78

**IOVERSOL INJECTION 74%**  
350 mg/mL Organically Bound Iodine

**Rx only**  
**1 syringe**

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

**Protect from light** - Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Do not remove syringe until ready for use.

Each mL contains 741 mg Ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Single dose syringe - Discard unused portion and syringe.**

**Medication and Fluid Pathway are sterile. Outside of syringe is not sterile.**

Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for Indications, dosage and dispensing information.

Manufactured by:  
Lieber-Fleishheim Company LLC  
Raleigh, NC 27616  
Made in USA

**Ultraject<sup>®</sup>**  
PREFILLED SYRINGE

**Guerbet** |

3378CT  
R10/21

3378CT  
R10/21

**Optiray<sup>®</sup> 350**      NDC 0019 1333 78      50 mL

**IOVERSOL INJECTION 74%**  
350 mg/mL Organically Bound Iodine

**Rx only**  
**1 syringe**

**For Intravenous and Intra-arterial Use Only**

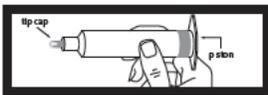
Not For Intrathecal Use

**Guerbet** |

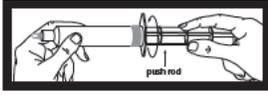
Push Here  
Then Lift To Open

3378CT  
R10/21

**Assembly and Inspection**      NOTE: Exterior of syringe is not sterile. Contents of syringe and area under tip cap and piston ribs are sterile and should be treated accordingly.



Remove syringe from carton and inspect the area around the tip cap and outside of piston for signs of leakage. Do not use if leakage is observed.



After screwing the push rod into the syringe piston, it is important to turn the push rod an additional 1/2 turn so that the piston rotates freely.



Prior to using the syringe, twist off tip cap and discard. The area under the tip cap is sterile, caution should now be used when handling. Syringe is now ready for needle or infusion tubing attachment.

R 10 / Z1

Lot: 3378CT  
Mfg/Exp: 08/2016 - 08/2017



Optiray<sup>®</sup> 350  
50 mL  
NDC 0019 1333 78  
Rx only  
1 syringe  
Guerbet |

IOVERSOL INJECTION 74%  
350 mg/mL Organically Bound Iodine  
Not For Intrathecal Use

50 mL  
NDC 0019 1333 78  
Rx only  
1 syringe  
Guerbet |

Optiray<sup>®</sup> 350  
IOVERSOL INJECTION 74%  
350 mg/mL Organically Bound Iodine  
For Intravenous and Intra-arterial Use Only  
Not For Intrathecal Use

GUERBET LLC  
3.375 X 1.406 X 6.125 - PRINTSIDE  
S170777 - 8/2/17  
GBT50HH

(b) (4)

3395CT  
R10/21

Lot:  
Mfg Exp:

3395CT  
R10/21

3395CT  
R10/21

### Optiray<sup>®</sup> 350

NDC 0019-1333-95

75 mL

#### IOVERSOL INJECTION 74%

350 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

Rx only

1 syringe

Guerbet | 

Push Here  
Then Lift to Open

### Optiray<sup>®</sup> 350

Single Dose Container  
Sterile Solution

NDC 0019-1333-95

75 mL

#### IOVERSOL INJECTION 74%

350 mg/mL Organically Bound Iodine

1 syringe Rx only

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

#### Ultraject<sup>®</sup>

PREFILLED SYRINGE  
FOR POWER INJECTION

Protect from light • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Do not remove syringe until ready for use.

Each mL contains 741 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

Single dose syringe • Discard unused portion and syringe.

Medication and Fluid Pathway are sterile. Outside of syringe is not sterile.

Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

Contains one sterile luer lock nut.

Recommended Dosage: See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616

Made in USA

Guerbet | 

Optiray<sup>®</sup> 350  
IOVERSOL INJECTION 74%  
350 mg/mL Organically Bound Iodine

Rx only  
1 syringe

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

3395CT  
R10/21

Guerbet | 

### Optiray<sup>®</sup> 350

NDC 0019-1333-95

75 mL

#### IOVERSOL INJECTION 74%

350 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

Rx only

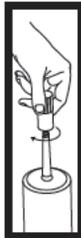
1 syringe

Guerbet | 



Please  
Recycle  
Carton

Attach luer lock nut to syringe by holding distal cover and screwing to the stop. Remove and discard distal cover when ready to attach sterile connector tubing.



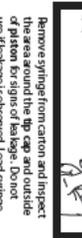
Next remove cap from luer lock nut and cover by twisting to break tamper evident seal. Discard cap.



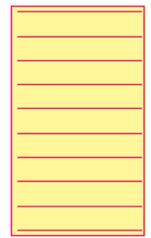
To remove tip cap from syringe, push in and twist off, then discard. The area under the cap is sterile. Cartons should now be used when handling.



Remove syringe from carton and inspect the syringe for any signs of damage or leakage. Do not use if leakage is observed. Load syringe into power injector.



**Assembly and Inspection**  
NOTE: Exterior of syringe is not sterile. Contents of syringe and area under tip cap and piston ribs are sterile and should be treated accordingly.



GUERBET LLC  
3.375 X 1.938 X 9.500 - PRINTSIDE  
S190958 - 10/1/19  
GBT125PI

(b) (4)

3390CT  
R10/21

Lot:  
Mfg/Exp:



### Optiray<sup>®</sup> 350

NDC 0019-1333-90 100 mL

#### IOVERSOL INJECTION 74%

350 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

Rx only

1 syringe

Guerbet |

Push Here  
Then Lift to Open

### Optiray<sup>®</sup> 350

Single Dose Container  
Sterile Solution

NDC 0019-1333-90 100 mL

#### IOVERSOL INJECTION 74%

350 mg/mL Organically Bound Iodine

1 syringe Rx only

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

**Ultraject<sup>®</sup>**  
PREFILLED SYRINGE  
FOR POWER INJECTION

Protect from light • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Do not remove syringe until ready for use.  
Each mL contains 741 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.  
Single dose syringe • Discard unused portion and syringe.  
Medication and Fluid Pathway are sterile. Outside of syringe is not sterile.  
Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.  
Contains one sterile luer lock nut.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616  
Made in USA

Guerbet |

Optiray<sup>®</sup> 350  
IOVERSOL INJECTION 74%  
350 mg/mL Organically Bound Iodine  
1 syringe  
Rx only  
For Intravenous and Intra-arterial Use Only  
Not For Intrathecal Use  
3390CT  
R10/21

Guerbet |

3390CT  
R10/21

### Optiray<sup>®</sup> 350

NDC 0019-1333-90 100 mL

#### IOVERSOL INJECTION 74%

350 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

Rx only

1 syringe

Guerbet |



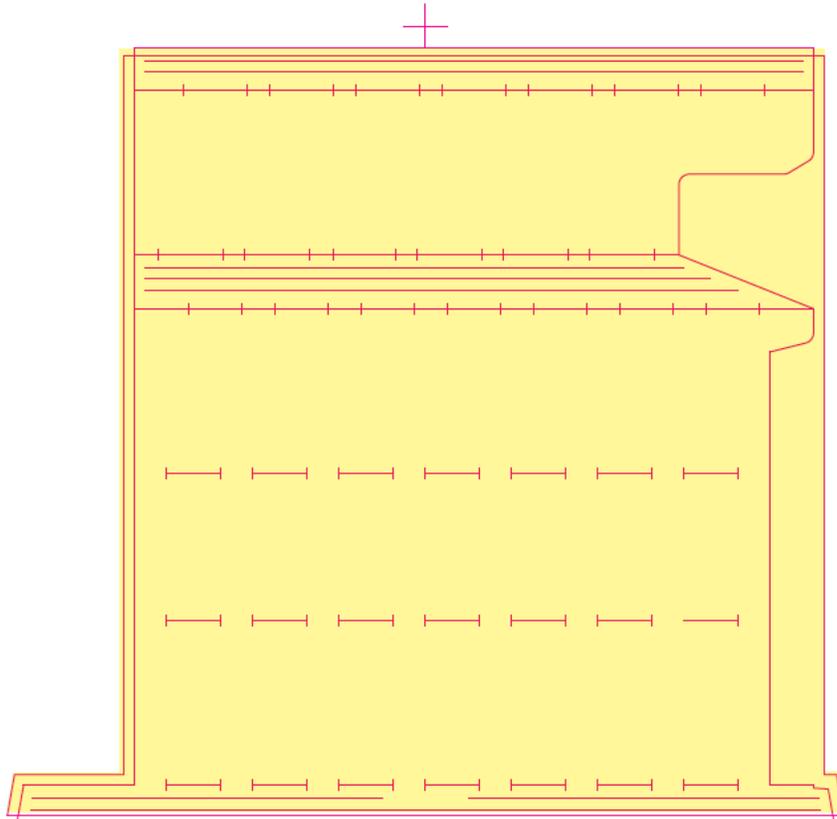
Please  
Recycle  
Carton



**Assembly and Inspection**  
NOTE: Exterior of syringe is not sterile.  
Contents of syringe and area under tip cap and piston flaps are sterile and should be treated accordingly.

GUERBET LLC  
3.375 X 1.938 X 9.500 - PRINTSIDE  
S190958 - 10/1/19  
GBT125PI

(b) (4)



GUERBET LLC  
3.375 X 1.938 X 9.500 - PRINTSIDE  
S190958 - 10/1/19  
GBT125PI

3387CT  
R10/21

**Optiray<sup>®</sup> 350** NDC 0019-1333-87 125 mL  
**IOVERSOL INJECTION 74%**  
350 mg/mL Organically Bound Iodine  
**Rx only**  
**1 syringe**  
**Guerbet** |

**For Intravenous and Intra-arterial Use Only**  
Not For Intrathecal Use

Push Here  
Then Lift to Open

Lot:  
Mfg Exp:

**Optiray<sup>®</sup> 350** Single Dose Container Sterile Solution NDC 0019-1333-87 125 mL  
**IOVERSOL INJECTION 74%**  
350 mg/mL Organically Bound Iodine  
**1 syringe Rx only**  
**For Intravenous and Intra-arterial Use Only**  
Not For Intrathecal Use  
**Ultraject<sup>®</sup>**  
PREFILLED SYRINGE FOR POWER INJECTION  
Protect from light • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Do not remove syringe until ready for use.  
Each mL contains 741 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.  
Single dose syringe • Discard unused portion and syringe.  
Medication and Fluid Pathway are sterile. Outside of syringe is not sterile.  
Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.  
Contains one sterile luer lock nut.  
Recommended Dosage: See Prescribing Information for indications, dosage and dispensing information.  
Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616  
Made in USA  
**Guerbet** |

**Optiray<sup>®</sup> 350** 125 mL NDC 0019-1333-87  
**IOVERSOL INJECTION 74%**  
350 mg/mL Organically Bound Iodine  
**Rx only**  
**1 syringe**  
**For Intravenous and Intra-arterial Use Only**  
Not For Intrathecal Use  
3387CT  
R10/21  
**Guerbet** |

3387CT  
R10/21

**Optiray<sup>®</sup> 350** NDC 0019-1333-87 125 mL  
**IOVERSOL INJECTION 74%**  
350 mg/mL Organically Bound Iodine  
**Rx only**  
**1 syringe**  
**Guerbet** |

**For Intravenous and Intra-arterial Use Only**  
Not For Intrathecal Use



**Assembly and Inspection**  
NOTE: Exterior of syringe is not sterile.  
Contents of syringe and area under tip cap and piston flaps are sterile and should be treated accordingly.  
  
  
  
  
**Assembly and Inspection**  
NOTE: Exterior of syringe is not sterile.  
Contents of syringe and area under tip cap and piston flaps are sterile and should be treated accordingly.

# Optiray<sup>®</sup> 350

Single Dose Container  
Sterile Solution

1333SYR

**Ioversol Injection 74%**  
350 mg/mL Organically Bound Iodine

**For Intravenous and  
Intra-arterial Use Only**

14210422

**Guerbet** | 

**Ultraject<sup>®</sup>** Rx only  
PREFILLED SYRINGE Not For  
Intrathecal Use

**Protect from light** - Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Do not remove syringe until ready for use.

Each mL contains 741 mg Ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Single dose syringe - Discard unused portion and syringe.**

**Medication and Fluid Pathway are sterile. Outside of syringe is not sterile.**

Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information. **Manufactured by:** Liebel-Farshem Company LLC, Raleigh, NC 27616 Made in USA

For Power Injection

NDC 0019 1333 78

20 x 50mL HH syringes

QTY: 20

EXP: MM/YYYY

LOT #: PPPPPPP

(30)20 (17)YYMMDD (10)PPPPPPPPPP

Secondary GS1 128 Linear Barcode

Primary GS1 128 Barcode

N(01) 1 03 0019 1333 78 S (30) 20

# Optiray<sup>®</sup> 350

Single Dose Container  
Sterile Solution

1333SYR

**Ioversol Injection 74%**  
350 mg/mL Organically Bound Iodine

**For Intravenous and  
Intra-arterial Use Only**

14210422

**Guerbet** | 

**Ultraject<sup>®</sup>** Rx only  
PREFILLED SYRINGE Not For  
Intrathecal Use

**Protect from light** - Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Do not remove syringe until ready for use.

Each mL contains 741 mg Ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Single dose syringe - Discard unused portion and syringe.**

**Medication and Fluid Pathway are sterile. Outside of syringe is not sterile.**

Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information. **Manufactured by:** Liebel-Farshem Company LLC, Raleigh, NC 27616 Made in USA

For Power Injection

NDC 0019 1333 95

20 x 75mL syringes

QTY: 20

EXP: MM/YYYY

LOT #: PPPPPPP

(30)20 (17)YYMMDD (10)PPPPPPPPPP

Secondary GS1 128 Linear Barcode

Primary GS1 128 Barcode

N(01) 1 03 0019 1333 95 S (30) 20

# Optiray<sup>®</sup> 350

Single Dose Container  
Sterile Solution

1333SYR

**Ioversol Injection 74%**  
350 mg/mL Organically Bound Iodine

**For Intravenous and  
Intra-arterial Use Only**

14210422

**Guerbet** | 

**Ultraject<sup>®</sup>** Rx only  
PREFILLED SYRINGE Not For  
Intrathecal Use

**Protect from light** - Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Do not remove syringe until ready for use.

Each mL contains 741 mg Ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Single dose syringe - Discard unused portion and syringe.**  
**Medication and Fluid Pathway are sterile. Outside of syringe is not sterile.**

Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information. **Manufactured by:** Liebel-Farshem Company LLC, Raleigh, NC 27616 Made in USA

For Power Injection

NDC 0019 1333 90

20 x 100mL syringes

QTY: 20

EXP: MM/YYYY

LOT #: PPPPPPP

(30)20 (17)YYMMDD (10)PPPPPPPPPP

Secondary GS1 128 Linear Barcode

Primary GS1 128 Barcode

N(01) 1 03 0019 1333 90 S (30) 20

# Optiray<sup>®</sup> 350

Single Dose Container  
Sterile Solution

1333SYR

**Ioversol Injection 74%**  
350 mg/mL Organically Bound Iodine

**For Intravenous and  
Intra-arterial Use Only**

14210422

**Guerbet** | 

**Ultraject<sup>®</sup>** Rx only  
PREFILLED SYRINGE Not For  
Intrathecal Use

**Protect from light** • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Do not remove syringe until ready for use.

Each mL contains 741 mg Ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Single dose syringe • Discard unused portion and syringe.**

**Medication and Fluid Pathway are sterile. Outside of syringe is not sterile.**

Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information. **Manufactured by:** Liebel-Farshem Company LLC, Raleigh, NC 27616 Made in USA

For Power Injection

NDC 0019 1333 87

20 x 125mL syringes

QTY: 20

EXP: MM/YYYY

LOT #: PPPPPPP

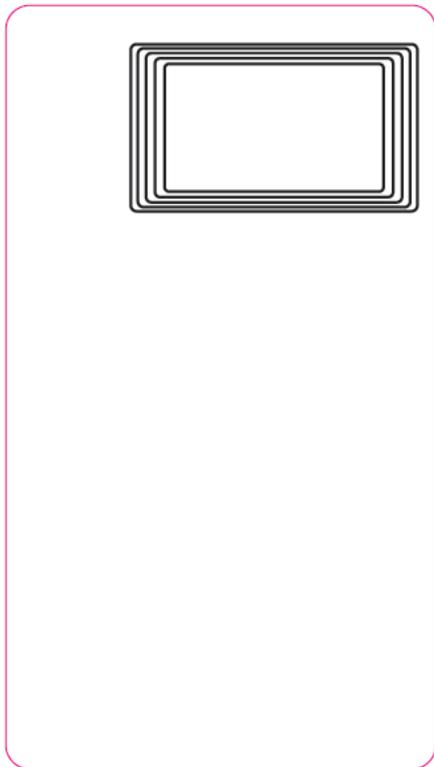
(30)20 (17)YYMMDD (10)PPPPPPPPPP

Secondary GS1 128 Linear Barcode

Primary GS1 128 Barcode

N(01) 1 03 0019 1333 87 S (30) 20

### RFID Tag Placement Only



Single Dose Container 100 mL NDC 0019-1333-00  
Sterile Solution

# Optiray® 350

**Ioversol Injection 74%**  
350 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only** Rx only Not For Intrathecal Use 

Each mL contains 741 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Medication and fluid pathway are sterile. Outside of syringe is not sterile. Single dose syringe. Discard unused portion and syringe. Protect from light.**

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616  
Made in USA

Guerbet | 

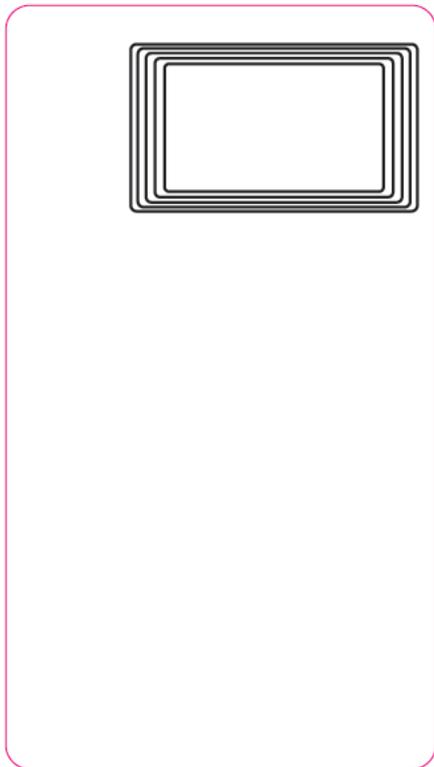
Lot:             
Mfg:             
Exp:           

16431021



3 00191 33300 1

### RFID Tag Placement Only



Single Dose Container 125 mL NDC 0019-1333-27  
Sterile Solution

## Optiray® 350

Ioversol Injection 74%  
350 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only** Rx only Not For Intrathecal Use 

Each mL contains 741 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Medication and fluid pathway are sterile. Outside of syringe is not sterile. Single dose syringe. Discard unused portion and syringe. Protect from light.**

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616  
Made in USA

Guerbet | 

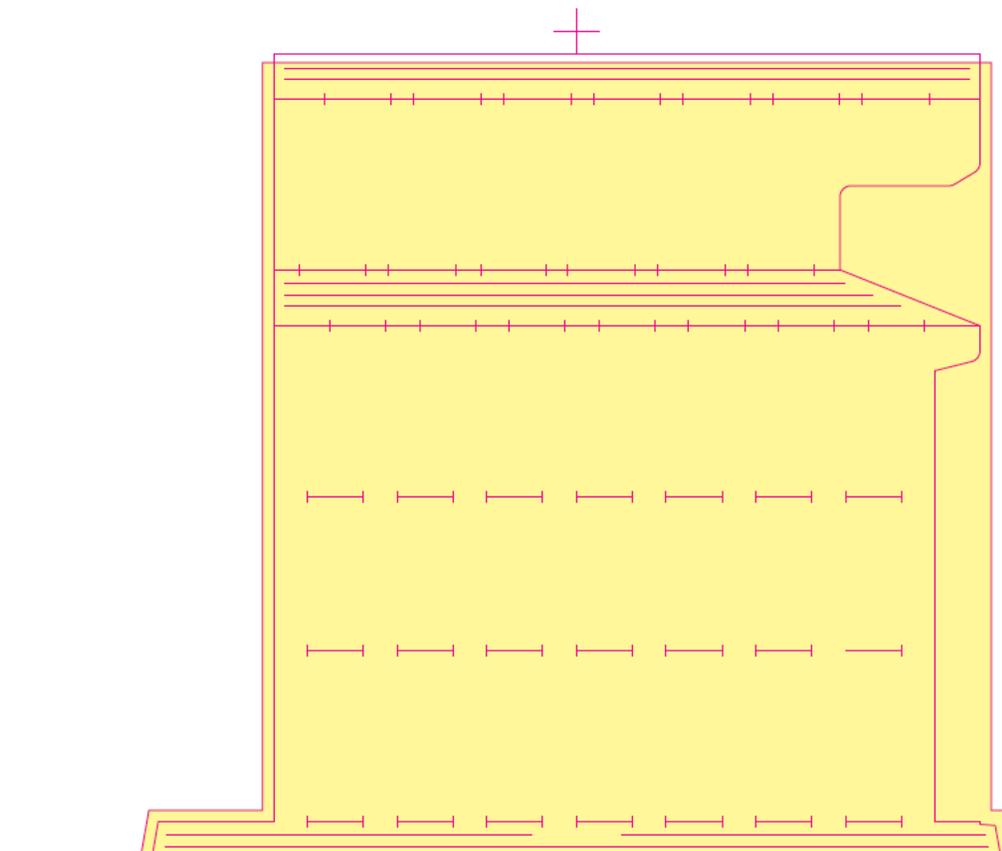
Lot:             
Mfg:             
Exp:           

16441021



3 00191 33327 8

(b) (4)



GUERBET LLC  
3.375 X 1.938 X 9.500 - PRINTSIDE  
S190958 - 10/1/19  
GBT125PI

3300CT  
R10/21

**Optiray® 350** NDC 0019-1333-00 100 mL  
**IOVERSOL INJECTION 74%**  
350 mg/mL Organically Bound Iodine  
**Rx only**  
1 syringe  
**For Intravenous and Intra-arterial Use Only**  
Not For Intrathecal Use  
Guerbet |

Push Here  
Then Lift to Open

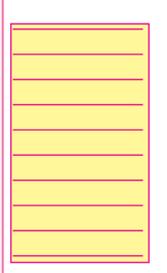


**Optiray® 350** Single Dose Container Sterile Solution NDC 0019-1333-00 100 mL  
**IOVERSOL INJECTION 74%**  
350 mg/mL Organically Bound Iodine  
**1 syringe Rx only**  
**For Intravenous and Intra-arterial Use Only**  
Not For Intrathecal Use  
**Ultraject®** PREILLED SYRINGE FOR POWER INJECTION   
Manufactured by:  
Lielbi-Franzheim Company LLC  
Raleigh, NC 27616  
Made in USA  
**Guerbet |**

**Optiray® 350** 100 mL  
**IOVERSOL INJECTION 74%**  
350 mg/mL Organically Bound Iodine  
**Rx only**  
1 syringe  
**For Intravenous and Intra-arterial Use Only**  
Not For Intrathecal Use  
**Guerbet |**   
3300CT  
R10/21

3300CT  
R10/21

**Optiray® 350** NDC 0019-1333-00 100 mL  
**IOVERSOL INJECTION 74%**  
350 mg/mL Organically Bound Iodine  
**Rx only**  
1 syringe  
**For Intravenous and Intra-arterial Use Only**  
Not For Intrathecal Use  
Guerbet |



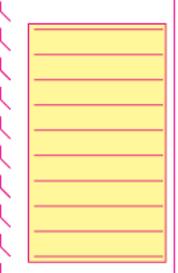
**Assembly and Inspection**  
**NOTE:** Exterior of syringe is not sterile. Contents of syringe and area under tip cap and piston are sterile and should be treated accordingly.

Attach luer lock nut to syringe by holding dust cover and screwing to the stop. Remove and discard dust cover when ready to attach sterile connector for tubing.

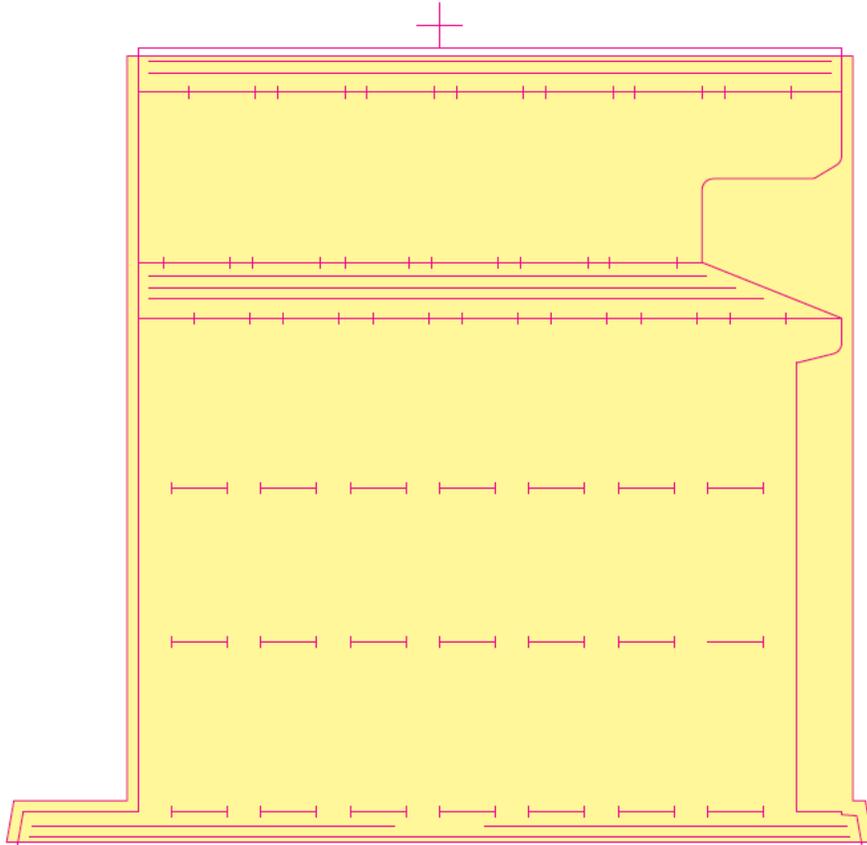
Remove cap from luer lock nut dust cover by pulling to break amp or evertical. Discard cap.

Remove cap from syringe, push in and twist off the distal end. Cap should now be used when handling.

Remove syringe from carton and inspect for signs of tampering. Cap and outside of the amp should be inspected for use. If leakage is observed, discard syringe into power injector.



(b) (4)



GUERBET LLC  
3.375 X 1.938 X 9.500 - PRINTSIDE  
S190958 - 10/1/19  
GBT125PI

**Optray® 350** NDC 0019-1333-27 125 mL

**IOVERSOL INJECTION 74%**  
350 mg/mL Organically Bound Iodine

**Rx only**  
**1 syringe**

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

**Guerbet** |

Push Here  
Then Lift to Open

**Optray® 350** Single Dose Container Sterile Solution NDC 0019-1333-27 125 mL

**IOVERSOL INJECTION 74%**  
350 mg/mL Organically Bound Iodine

**1 syringe Rx only**

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

**Ultraject®** PREFILLED SYRINGE FOR POWER INJECTION

**RFID Technology**

**Guerbet** |

Protect from light • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].  
Do not remove syringe until ready for use.  
Each mL contains 741 mg Ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.  
Single dose syringe • Discard unused portion and syringe.  
Medication and Fluid Pathway are sterile. Outside of syringe is not sterile.  
Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.  
Contains one sterile luer lock nut.  
Recommended Dosage: See Prescribing Information for Indications, dosage and dispensing information.  
Manufactured by:  
Uebel-Fleishheim Company LLC  
Raleigh, NC 27616  
Made in USA

**Optray® 350** 125 mL NDC 0019-1333-27

**IOVERSOL INJECTION 74%**  
350 mg/mL Organically Bound Iodine

**Rx only**  
**1 syringe**

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

**Guerbet** |

**Optray® 350** NDC 0019-1333-27 125 mL

**IOVERSOL INJECTION 74%**  
350 mg/mL Organically Bound Iodine

**Rx only**  
**1 syringe**

**For Intravenous and Intra-arterial Use Only**

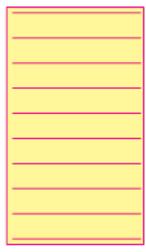
Not For Intrathecal Use

**Guerbet** |

Please Recycle Carton

**Assembly and Inspection**

**NOTE:** Exterior of syringe is not sterile. Contents of syringe and area under tip cap and piston are sterile and should be treated accordingly.



# Optiray<sup>®</sup> 350

Single Dose Container  
Sterile Solution

1333RFID

**Ioversol Injection 74%**  
350 mg/mL Organically Bound Iodine

**For Intravenous and  
Intra-arterial Use Only**

 **RFID Technology**  
**Ultraject<sup>®</sup>**  
PREFILLED SYRINGE  
FOR POWER INJECTION

**Guerbet** |   
**Rx only**  
Not For  
Intrathecal Use

33015901 R0422

**Protect from light** - Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Do not remove syringe until ready for use.

Each mL contains 741 mg Ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Single dose syringe - Discard unused portion and syringe.**

**Medication and Fluid Pathway are sterile. Outside of syringe is not sterile.**

Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information. **Manufactured by:** Liebel-Flarsheim Company LLC, Raleigh, NC 27616 **Made in USA**

For Power Injection

NDC 0019 1333 00

20 x 100mL syringes

QTY: 20

EXP: MM/YYYY

LOT #: P P P P P P P P

(30)20 (17)YYMMDD (10)P P P P P P P P P P

Secondary GS1 128 Linear Barcode

Primary GS1 128 Barcode

N(01) 1 03 0019 1333 00 S (30) 20

# Optiray® 350

Single Dose Container  
Sterile Solution

1333RFID

**Ioversol Injection 74%**  
350 mg/mL Organically Bound Iodine

**For Intravenous and  
Intra-arterial Use Only**

 **RFID Technology**  
**Ultraject®**  
PREFILLED SYRINGE  
FOR POWER INJECTION

**Guerbet**   
Rx only  
Not For  
Intrathecal Use

33015901 R0422

**Protect from light** - Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Do not remove syringe until ready for use.

Each mL contains 741 mg Ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Single dose syringe - Discard unused portion and syringe.**

**Medication and Fluid Pathway are sterile. Outside of syringe is not sterile.**

Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information. **Manufactured by:** Liebel-Flarsheim Company LLC, Raleigh, NC 27616 **Made in USA**

For Power Injection

NDC 0019 1333 27

20 x 125mL syringes

QTY: 20

EXP: MM/YYYY

LOT #: P P P P P P P P

(30)20 (17)YYMMDD (10)P P P P P P P P P P

Secondary GS1 128 Linear Barcode

Primary GS1 128 Barcode

N(01) 1 03 0019 1333 27 S (30) 20

<b>Optiray<sup>®</sup> 320</b>		Single-Dose Container Sterile Solution	20 mL NDC 0019-1323-02
<b>Ioversol Injection 68%</b> 320 mg/mL Organically Bound Iodine		Protect from light • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Discard contents if product is frozen or if crystallization occurs. Each mL contains 678 mg Ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.	
<b>For Intravenous and Intra-arterial Use Only</b>	<b>Rx only</b> Not For Intrathecal Use	<b>Single dose container • Discard unused portion</b>	
Lot:		<b>Recommended Dosage:</b> See Prescribing Information for indications, dosage and dispensing information.	
Mfg:		Manufactured by: <b>Guerbet</b>   	
Exp:		Lieber-Franke Company LLC Raleigh, NC 27616 Made in USA 10011021	

2019-1323-02



Lot: [REDACTED]

Mfg: [REDACTED]

Exp: [REDACTED]

Single-Dose Container  
Sterile Solution

## Optiray<sup>®</sup> 320

50 mL  
NDC 0019-1323-06

**Rx only**  
Not For  
Intrathecal Use

**Guerbet** |

**Ioversol Injection 68%**  
320 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only**

**Protect from light** • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Discard contents if product is frozen or if crystallization occurs.  
Each mL contains 678 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer.  
The pH is adjusted with hydrochloric acid or sodium hydroxide.  
**Single dose container • Discard unused portion**  
**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

10031021

Manufactured by:  
Lieber-Farshem Company LLC  
Raleigh, NC 27616  
Made in USA

50 mL  
NDC 0019-1323-06

**Optiray<sup>®</sup> 320**  
Single-Dose Container  
Sterile Solution

00191-1323-06

05

57

001

Lot

Mfg

Exp

**Single-Dose Container**  
Sterile Solution

**Optiray® 320**

**Ioversol Injection 68%**  
320 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only**

**100 mL**  
NDC 0019-1323-11

10041021



**Rx only**  
Not For  
Intrathecal Use

**Guerbet** | 

Manufactured by:  
Liebel-Flansheim Company LLC  
Raleigh, NC 27616  
Made in USA

**Protect from light** • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F)  
[see USP Controlled Room Temperature]. Discard contents if product is frozen or if crystallization occurs.  
Each mL contains 678 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.  
**Single dose container • Discard unused portion**  
**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

**Optiray® 320**  
Single-Dose Container  
Sterile Solution  
100 mL  
NDC 0019-1323-11

**Ioversol Injection 68%**

25

50

75

8

**SZ**  
125

**00L**  
100

**SZL**  
75

**0SL**  
50

**25**

**Single-Dose Container**  
Sterile Solution

# Optiray® 320

**loversol Injection 68%**  
320 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only**

**Protect from light** • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Discard contents if product is frozen or if crystallization occurs. Each mL contains 678 mg loversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.  
**Single dose container • Discard unused portion**  
**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

10051021

Manufactured by:  
Lieber-Fleishheim Company LLC  
Raleigh, NC 27616  
Made in USA

**150 mL**  
NDC 0019-1323-16

Lot: XXXXXXXXXX

Mfg: XXXXXXXXXX

Exp: XXXXXXXXXX

**Rx only**  
Not For  
Intrathecal Use

**Guerbet** |

3 0 0 1 9 1 3 2 3 1 6 3

00L  
125  
150  
175  
200

Single-Dose Container  
Sterile Solution

# Optiray® 320

200 mL  
NDC 0019-1323-21

Lot: [Redacted]  
Mfg: [Redacted]  
Exp: [Redacted]

## loversol Injection 68%

320 mg/mL Organically Bound Iodine

For Intravenous and Intra-arterial Use Only

200  
175  
150  
125  
100  
75  
50

**Rx only**  
Not For  
Intrathecal Use

**Protect from light** • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Discard contents if product is frozen or if crystallization occurs.  
Each mL contains 678 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.  
**Single dose container • Discard unused portion**  
**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.



**Guerbet** |   
10061021

loversol Injection 68%

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616  
Made in USA

200 mL  
NDC 0019-1323-21

Optiray® 320

Single-Dose Container  
Sterile Solution



(b) (4)

# Optiray® 320

**Ioversol Injection 68%**  
320 mg/mL Organically Bound Iodine

**For Intravenous and  
Intra-arterial Use Only**

Not For Intrathecal Use  
**Rx only**

23US890L0422

Single-Dose Container  
Sterile Solution

1323B0T

**Protect from light** • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].  
Discard contents if product is frozen or if crystallization occurs.

**Single dose containers • Discard unused portion**

Each mL contains 678 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer.  
The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616  
Made in USA

**Guerbet** |

25 x 20 mL bottles

SKU: 132302

EXP: MM/YYYY    LOT: P P P P P P P P    QTY: 25    MFG: MM/YYYY

Linear Barcode

(17)YYMMDD(10)PPPPPPPP(30)XX(11)YYMMDD

NDC 0019-1323-02

GTIN-14 Barcode



(b) (4)

# Optiray® 320

**Ioversol Injection 68%**  
320 mg/mL Organically Bound Iodine

**For Intravenous and  
Intra-arterial Use Only**

Not For Intrathecal Use  
**Rx only**

23US890L0422

Single-Dose Container  
Sterile Solution

1323B0T

**Protect from light** • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].  
Discard contents if product is frozen or if crystallization occurs.

**Single dose containers • Discard unused portion**

Each mL contains 678 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer.  
The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616  
Made in USA

**Guerbet** |

25 x 50 mL bottles

SKU: 132306

EXP: MM/YYYY    LOT: P P P P P P P P    QTY: 25    MFG: MM/YYYY

Linear Barcode

(17)YYMMDD(10)PPPPPPPP(30)XX(11)YYMMDD

NDC 0019-1323-06

GTIN-14 Barcode

# Optiray® 320

**Ioversol Injection 68%**  
320 mg/mL Organically Bound Iodine

**For Intravenous and  
Intra-arterial Use Only**

Not For Intrathecal Use  
**Rx only**

23US890L0422

Single-Dose Container  
Sterile Solution

1323B0T

**Protect from light** • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].  
Discard contents if product is frozen or if crystallization occurs.

**Single dose containers • Discard unused portion**

Each mL contains 67.8 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer.  
The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Lieber-Franzheim Company LLC  
Raleigh, NC 27616  
Made in USA

**Guerbet** | 

12 x 100 mL bottles

SKU: 132311

EXP: MM/YYYY    LOT: P P P P P P P P    QTY: 12    MFG: MM/YYYY

Linear Barcode

(17)YYMMDD(10)PPPPPPPP(30)XX(11)YYMMDD

NDC 0019-1323-11

GTIN-14 Barcode

(b) (4)

# Optiray® 320

**Ioversol Injection 68%**  
320 mg/mL Organically Bound Iodine

**For Intravenous and  
Intra-arterial Use Only**

Not For Intrathecal Use  
**Rx only**

23US890L0422

Single-Dose Container  
Sterile Solution

1323B0T

**Protect from light** • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].  
Discard contents if product is frozen or if crystallization occurs.

**Single dose containers • Discard unused portion**

Each mL contains 678 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer.  
The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616  
Made in USA

**Guerbet** | 

12 x 150 mL bottles

SKU: 132316

EXP: MM/YYYY    LOT: P P P P P P P P    QTY: 12    MFG: MM/YYYY

Linear Barcode

(17)YYMMDD(10)PPPPPPPP(30)XX(11)YYMMDD

NDC 0019-1323-16

GTIN-14 Barcode

# Optiray® 320

**Ioversol Injection 68%**  
320 mg/mL Organically Bound Iodine

**For Intravenous and  
Intra-arterial Use Only**

Not For Intrathecal Use  
**Rx only**

23US890L0422

Single-Dose Container  
Sterile Solution

1323B0T

**Protect from light** • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].  
Discard contents if product is frozen or if crystallization occurs.

**Single dose containers • Discard unused portion**

Each mL contains 678 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer.  
The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616  
Made in USA

**Guerbet** | 

12 x 200 mL bottles

SKU: 132321

EXP: MM/YYYY    LOT: P P P P P P P P    QTY: 12    MFG: MM/YYYY

Linear Barcode

(17)YYMMDD(10)PPPPPPPP(30)XX(11)YYMMDD

NDC 0019-1323-21

GTIN-14 Barcode

(b) (4)



Single Dose Container  
Sterile Solution

# Optiray<sup>®</sup> 320

50 mL  
NDC 0019-1323-78

**Ioversol Injection 68%**  
320 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only**

**Rx only**

Not For Intrathecal Use

**Medication and fluid pathway are sterile. Outside of syringe is not sterile.**

**Single dose syringe • Discard unused portion and syringe.**

**Protect from light • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F)** [see USP Controlled Room Temperature].

Each mL contains 678 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616 Made in USA

**Guerbet**



Lot:  
Mfg:  
Exp:

15471021

Single Dose Container 50 mL  
Sterile Solution NDC 0019-1323-52

# Optiray® 320

**Ioversol Injection 68%**  
320 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only** **Rx only**

Not For Intrathecal Use

**Medication and fluid pathway are sterile.**  
**Outside of syringe is not sterile.**  
**Single dose syringe • Discard unused portion and syringe.**  
**Protect from light • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].**

Each mL contains 678 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide. Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616 Made in USA

Lot:    
Mfg:    
Exp:  

Guerbet | 

154810.21



3 00191 32352 1

Single Dose Container 75 mL  
Sterile Solution NDC 0019-1323-95

# Optiray<sup>®</sup> 320

**Ioversol Injection 68%**  
320 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only** **Rx only**

Not For Intrathecal Use

**Medication and fluid pathway are sterile.**  
**Outside of syringe is not sterile.**  
**Single dose syringe - Discard unused portion and syringe.**  
**Protect from light** - Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].  
Each mL contains 678 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide. Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.  
**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616 Made in USA

Lot:    
Mfg:    
Exp:  

Guerbet | 

154910.21



3 00191 32395 8

Single Dose Container  
Sterile Solution

100 mL  
NDC 0019-1323-90

# Optiray® 320

**Ioversol Injection 68%**  
320 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only**    **Rx only**

Not For Intrathecal Use

**Medication and fluid pathway are sterile. Outside of syringe is not sterile.  
Single dose syringe • Discard unused portion and syringe.**

**Protect from light** • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F)  
[see USP Controlled Room Temperature].

Each mL contains 678 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide. Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616    Made in USA

**Guerbet** | 



Lot:  
Mfg:  
Exp:

15501021

Single Dose Container  
Sterile Solution

125 mL  
NDC 0019-1323-87

# Optiray<sup>®</sup> 320

**Ioversol Injection 68%**  
320 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only**     **Rx only**

Not For Intrathecal Use

**Medication and fluid pathway are sterile. Outside of syringe is not sterile.  
Single dose syringe • Discard unused portion and syringe.**

**Protect from light** • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F)  
[see USP Controlled Room Temperature].

Each mL contains 678 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide. Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616    Made in USA

**Guerbet** | 



Lot:  
Mfg:  
Exp:

15511021

R 10 / Z1

23 78CT

**Optiray® 320** 50 mL

NDC 0019 1323 78

**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine

**Rx only**  
1 syringe

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

Please Recycle Carton

Not For Intrathecal Use

**For Intravenous and Intra-arterial Use Only**

IOVERSOL INJECTION 68%  
320 mg/mL Organically Bound Iodine

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2378CT  
R10/21

**Optiray® 320** 50 mL

NDC 0019 1323 78

**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine

**Rx only**  
1 syringe

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

Protect from light - Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Do not remove syringe until ready for use.

Each mL contains 678 mg Ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

Single dose syringe - Discard unused portion and syringe.

Medication and Fluid Pathway are sterile. Outside of syringe is not sterile.

Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

Recommended Dosage: See Prescribing Information for Indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616  
Made in USA

**Ultraject®**  
PREFILLED SYRINGE

**Guerbet**

50 mL  
NDC 0019 1323 78

**Rx only**  
1 syringe

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

---

2378CT  
R10/21

**Optiray® 320** 50 mL

NDC 0019 1323 78

**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine

**Rx only**  
1 syringe

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

Push Here  
Then Lift To Open

50 mL  
NDC 0019 1323 78

**Rx only**  
1 syringe

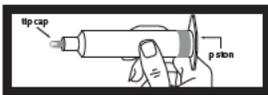
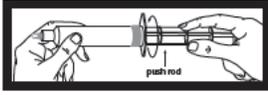
**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

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**Assembly and Inspection**

NOTE: Exterior of syringe is not sterile. Contents of syringe and area under tip cap and piston ribs are sterile and should be treated accordingly.


Remove syringe from carton and inspect the area around the tip cap and outside of piston for signs of leakage. Do not use if leakage is observed.

After screwing the push rod into the syringe piston, it is important to turn the push rod an additional 1/2 turn so that the piston rotates freely.

Prior to using the syringe, twist off tip cap and discard. The area under the tip cap is sterile, caution should now be used when handling. Syringe is now ready for needle or infusion tubing attachment.

GUERBET LLC  
3.375 X 1.406 X 6.125 - PRINTSIDE  
S170777 - 8/2/17  
GBT50HH

Reference ID: 4978954

(b) (4)

GUERBET LLC  
3.375 X 1.938 X 9.500 - PRINTSIDE  
S190958 - 10/1/19  
GBT125PI

2352CT  
R10/21
Push Here  
Then Lift to Open

## Optiray® 320

NDC 0019-1323-52     50 mL

**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine

For Intravenous and Intra-arterial Use Only

Not For Intrathecal Use

**Rx only**

**1 syringe**

**Guerbet** |

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Mfg/Exp:     Lot:

## Optiray® 320

Single Dose Container     Sterile Solution     NDC 0019-1323-52     50 mL

50 mL  
incomplete

**Rx only**

**1 syringe**

**Guerbet** |

**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine

**1 syringe     Rx only**

For Intravenous and Intra-arterial Use Only

Not For Intrathecal Use

**Ultraject®**  
PREFILLED SYRINGE  
FOR POWER INJECTION

Protect from light • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Do not remove syringe until ready for use.

Each mL contains 678 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

Single dose syringe • Discard unused portion and syringe.

Medication and Fluid Pathway are sterile. Outside of syringe is not sterile.

Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed. Contains one sterile luer lock nut.

Recommended Dosage: See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616

Made in USA

2352CT  
R10/21

## Optiray® 320

NDC 0019-1323-52     50 mL

Please  
Recycle  
Carton

2352CT  
R10/21

**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine

For Intravenous and Intra-arterial Use Only

Not For Intrathecal Use

**Rx only**

**1 syringe**

**Guerbet** |

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2352CT  
R10/21

**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine

For Intravenous and Intra-arterial Use Only

Not For Intrathecal Use

**Rx only**

**1 syringe**

**Guerbet** |

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2352CT  
R10/21

**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine

For Intravenous and Intra-arterial Use Only

Not For Intrathecal Use

**Rx only**

**1 syringe**

**Guerbet** |

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2352CT  
R10/21

**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine

For Intravenous and Intra-arterial Use Only

Not For Intrathecal Use

**Rx only**

**1 syringe**

**Guerbet** |

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2352CT  
R10/21

**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine

For Intravenous and Intra-arterial Use Only

Not For Intrathecal Use

**Rx only**

**1 syringe**

**Guerbet** |

---

2352CT  
R10/21

**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine

For Intravenous and Intra-arterial Use Only

Not For Intrathecal Use

**Rx only**

**1 syringe**

**Guerbet** |

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2352CT  
R10/21

**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine

For Intravenous and Intra-arterial Use Only

Not For Intrathecal Use

**Rx only**

**1 syringe**

**Guerbet** |

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2352CT  
R10/21

**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine

For Intravenous and Intra-arterial Use Only

Not For Intrathecal Use

**Rx only**

**1 syringe**

**Guerbet** |

---

2352CT  
R10/21

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Not For Intrathecal Use

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**Guerbet** |

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**1 syringe**

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**1 syringe**

**Guerbet** |

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R10/21

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**1 syringe**

**Guerbet** |

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**1 syringe**

**Guerbet** |

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**1 syringe**

**Guerbet** |

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R10/21

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Not For Intrathecal Use

**Rx only**

**1 syringe**

**Guerbet** |

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R10/21

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320 mg/mL Organically Bound Iodine

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Not For Intrathecal Use

**Rx only**

**1 syringe**

**Guerbet** |

---

2352CT  
R10/21

**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine

For Intravenous and Intra-arterial Use Only

Not For Intrathecal Use

**Rx only**

**1 syringe**

**Guerbet** |

---

2352CT  
R10/21

**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine

For Intravenous and Intra-arterial Use Only

Not For Intrathecal Use

**Rx only**

**1 syringe**

**Guerbet** |

---

2352CT  
R10/21

**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine

(b) (4)

2395CT  
R10/21

Lot:  
Mfg/Exp:



2395CT  
R10/21

### Optiray® 320

NDC 0019-1323-95

75 mL

#### IOVERSOL INJECTION 68%

320 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

Rx only

1 syringe

Guerbet |

Push Here  
Then Lift to Open

### Optiray® 320

Single Dose Container  
Sterile Solution

NDC 0019-1323-95

75 mL

#### IOVERSOL INJECTION 68%

320 mg/mL Organically Bound Iodine

**1 syringe Rx only**

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

**Ultraject®**  
PREFILLED SYRINGE  
FOR POWER INJECTION

Protect from light • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Do not remove syringe until ready for use.  
Each mL contains 678 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.  
Single dose syringe • Discard unused portion and syringe.  
Medication and Fluid Pathway are sterile. Outside of syringe is not sterile.  
Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.  
Contains one sterile luer lock nut.  
Recommended Dosages: See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616  
Made in USA

Guerbet |

2395CT  
R10/21

**Optiray® 320**  
IOVERSOL INJECTION 68%  
320 mg/mL Organically Bound Iodine  
**Rx only**  
**1 syringe**  
**For Intravenous and Intra-arterial Use Only**  
Not For Intrathecal Use  
2395CT  
R10/21

### Optiray® 320

NDC 0019-1323-95

75 mL

#### IOVERSOL INJECTION 68%

320 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

Rx only

1 syringe

Guerbet |



Please  
Recycle  
Carton

Attach luer lock nut to syringe by holding dust cover and screwing to the stop. Remove and discard dust cover when ready to attach sterile connector tubing.



Heat remove cap from luer lock nut dust cover by twisting to break tamper evident seal. Discard cap.



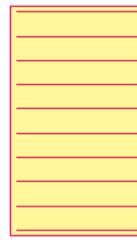
To remove tip cap from syringe, push in and twist off, then discard. The area under the cap is sterile. Cartons should now be used when handling.



Remove syringe from carton and inspect the syringe for any signs of damage or leakage. Do not use if leakage is observed. Load syringe into power injector.



**Assembly and Inspection**  
NOTE: Exterior of syringe is not sterile. Contents of syringe and area under tip cap and piston ribs are sterile and should be treated accordingly.



GUERBET LLC  
3.375 X 1.938 X 9.500 - PRINTSIDE  
S190958 - 10/1/19  
GBT125PI

(b) (4)

3.375 X 1.938 X 9.500 – PRINTSIDE  
 S190958 – 10/1/19  
 GBT125PI

**Optiray® 320** NDC 0019-1323-90 100 mL

**IOVERSOL INJECTION 68%**  
 320 mg/mL Organically Bound Iodine

**1 syringe** Rx only

**Guerbet** |

**For Intravenous and Intra-arterial Use Only**  
 Not For Intrathecal Use

Push Here  
Then Lift to Open

---

2390CT  
R10/21

**Optiray® 320** Single Dose Container Sterile Solution NDC 0019-1323-90 100 mL

**IOVERSOL INJECTION 68%**  
 320 mg/mL Organically Bound Iodine

**1 syringe** Rx only

**Guerbet** |

**For Intravenous and Intra-arterial Use Only**  
 Not For Intrathecal Use

**Ultraject®**  
 PREFILLED SYRINGE FOR POWER INJECTION

Manufactured by:  
 Liebel-Flarsheim Company LLC  
 Raleigh, NC 27616  
 Made in USA

100 mL  
100 mg/mL  
IOVERSOL INJECTION 68%  
320 mg/mL Organically Bound Iodine

**Rx only**  
**1 syringe**

**Guerbet** |

**For Intravenous and Intra-arterial Use Only**  
 Not For Intrathecal Use

2390CT  
R10/21

---

2390CT  
R10/21

**Optiray® 320** NDC 0019-1323-90 100 mL

**IOVERSOL INJECTION 68%**  
 320 mg/mL Organically Bound Iodine

**1 syringe** Rx only

**Guerbet** |

**For Intravenous and Intra-arterial Use Only**  
 Not For Intrathecal Use

Please Recycle Carton

---

**Assembly and Inspection**

NOTE: Exterior of syringe is not sterile. Contents of syringe and area under tip cap and piston (as are sterile and should be treated accordingly)

**Assembly and Inspection**

NOTE: Exterior of syringe is not sterile. Contents of syringe and area under tip cap and piston (as are sterile and should be treated accordingly)

(b) (4)

GUERBET LLC  
3.375 X 1.938 X 9.500 - PRINTSIDE  
S190958 - 10/1/19  
GBT125PI

**Optiray® 320** NDC 0019-1323-87 125 mL

**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

**Rx only**

**1 syringe**

**Guerbet** |

Push Here  
Then Lift to Open

---

Mfg/Exp:

Lot:

**Optiray® 320** Single Dose Container  
Sterile Solution NDC 0019-1323-87 125 mL

**125 mL**

**Rx only**

**1 syringe**

**Guerbet** |

**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine

**1 syringe** **Rx only**

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

**Ultraject®**  
PREFILLED SYRINGE  
FOR POWER INJECTION

Protect from light • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Do not remove syringe until ready for use.

Each mL contains 678 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

Single dose syringe • Discard unused portion and syringe.

Medication and Fluid Pathway are sterile. Outside of syringe is not sterile.

Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed. Contains one sterile luer lock nut.

Recommended Dosage: See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616

Made in USA

**Guerbet** |

---

2387CT  
R10/21

**Optiray® 320** NDC 0019-1323-87 125 mL

**125 mL**

**Rx only**

**1 syringe**

**Guerbet** |

**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

**Rx only**

**1 syringe**

**Guerbet** |

Please Recycle Carton

---

Attach luer lock nut to syringe by holding dust cover and screwing to the stop. Remove and discard dust cover when ready to attach sterile connector tubing.

Heat remove cap from luer lock nut dust cover by twisting to break tamper evident seal. Discard cap.

To remove tip cap from syringe, push in and twist off, then discard. The area under the cap is sterile. Cartridges should now be used when handling.

Remove syringe from carton and inspect the syringe for any damage. The piston of piston for signs of leakage. Do not use if leakage is observed. Load syringe into power injector.

**Assembly and Inspection**

NOTE: Exterior of syringe is not sterile. Contents of syringe and area under tip cap and piston flaps are sterile and should be treated accordingly.

Reference ID: A978954

# Optiray<sup>®</sup> 320

Single Dose Container  
Sterile Solution

1323SYR

**Ioversol Injection 68%**  
320 mg/mL Organically Bound Iodine

**For Intravenous and  
Intra-arterial Use Only**

14220422

Guerbet | 

**Ultraject<sup>®</sup>** Rx only  
PREFILLED SYRINGE Not For  
Intrathecal Use

**Protect from light** - Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Do not remove syringe until ready for use.

Each mL contains 678 mg Ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Single dose syringe - Discard unused portion and syringe.**

**Medication and Fluid Pathway are sterile. Outside of syringe is not sterile.**

Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information. **Manufactured by:** Liebel-Farshem Company LLC, Raleigh, NC 27616 Made in USA

For Power Injection

NDC 0019 1323 78

20 x 50mL HH syringes

QTY: 20

EXP: MM/YYYY

LOT #: PPPPPPP

(30)20 (17)YYMMDD (10)PPPPPPPPPP

Secondary GS1 128 Linear Barcode

Primary GS1 128 Barcode

N(01) 1 03 0019 1323 78 S (30) 20

# Optiray<sup>®</sup> 320

Single Dose Container  
Sterile Solution

1323SYR

**Ioversol Injection 68%**  
320 mg/mL Organically Bound Iodine

**For Intravenous and  
Intra-arterial Use Only**

14220422

Guerbet | 

**Ultraject<sup>®</sup>** Rx only  
PREFILLED SYRINGE Not For  
Intrathecal Use

**Protect from light** - Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Do not remove syringe until ready for use.

Each mL contains 678 mg Ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Single dose syringe - Discard unused portion and syringe. Medication and Fluid Pathway are sterile. Outside of syringe is not sterile.**

Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information. **Manufactured by:** Liebel-Farshem Company LLC, Raleigh, NC 27616 Made in USA

For Power Injection

NDC 0019 1323 52

20 x 50mL syringes

QTY: 20

EXP: MM/YYYY

LOT #: PPPPPPP

(30)20 (17)YYMMDD (10)PPPPPPPPPP

Secondary GS1 128 Linear Barcode

Primary GS1 128 Barcode

N(01) 1 03 0019 1323 52 S (30) 20

# Optiray<sup>®</sup> 320

Single Dose Container  
Sterile Solution

1323SYR

**Ioversol Injection 68%**  
320 mg/mL Organically Bound Iodine

**For Intravenous and  
Intra-arterial Use Only**

14220422

Guerbet | 

**Ultraject<sup>®</sup>** Rx only  
PREFILLED SYRINGE Not For  
Intrathecal Use

**Protect from light** - Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Do not remove syringe until ready for use.

Each mL contains 678 mg Ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Single dose syringe - Discard unused portion and syringe.**

**Medication and Fluid Pathway are sterile. Outside of syringe is not sterile.**

Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information. **Manufactured by:** Liebel-Farshem Company LLC, Raleigh, NC 27616 Made in USA

For Power Injection

NDC 0019 1323 95

20 x 75mL syringes

QTY: 20

EXP: MM/YYYY

LOT #: PPPPPPP

(30)20 (17)YYMMDD (10)PPPPPPPPPP

Secondary GS1 128 Linear Barcode

Primary GS1 128 Barcode

N(01) 1 03 0019 1323 95 S (30) 20

# Optiray<sup>®</sup> 320

Single Dose Container  
Sterile Solution

1323SYR

**Ioversol Injection 68%**  
320 mg/mL Organically Bound Iodine

**For Intravenous and  
Intra-arterial Use Only**

14220422

Guerbet | 

**Ultraject<sup>®</sup>** Rx only  
PREFILLED SYRINGE Not For  
Intrathecal Use

**Protect from light** - Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Do not remove syringe until ready for use.

Each mL contains 678 mg Ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Single dose syringe - Discard unused portion and syringe.**

**Medication and Fluid Pathway are sterile. Outside of syringe is not sterile.**

Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information. **Manufactured by:** Liebel-Farshem Company LLC, Raleigh, NC 27616 Made in USA

For Power Injection

NDC 0019 1323 90

20 x 100mL syringes

QTY: 20

EXP: MM/YYYY

LOT #: PPPPPPP

(30)20 (17)YYMMDD (10)PPPPPPPPPP

Secondary GS1 128 Linear Barcode

Primary GS1 128 Barcode

N(01) 1 03 0019 1323 90 S (30) 20

# Optiray<sup>®</sup> 320

Single Dose Container  
Sterile Solution

1323SYR

**Ioversol Injection 68%**  
320 mg/mL Organically Bound Iodine

**For Intravenous and  
Intra-arterial Use Only**

14220422

Guerbet | 

**Ultraject<sup>®</sup>** Rx only  
PREFILLED SYRINGE Not For  
Intrathecal Use

**Protect from light** - Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Do not remove syringe until ready for use.

Each mL contains 678 mg Ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Single dose syringe - Discard unused portion and syringe.**

**Medication and Fluid Pathway are sterile. Outside of syringe is not sterile.**

Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information. **Manufactured by:** Liebel-Farshem Company LLC, Raleigh, NC 27616 Made in USA

For Power Injection

NDC 0019 1323 87

20 x 125mL syringes

QTY: 20

EXP: MM/YYYY

LOT #: PPPPPPP

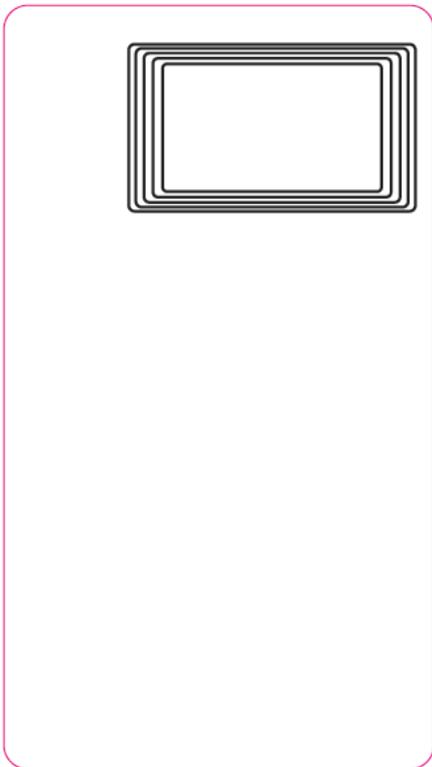
(30)20 (17)YYMMDD (10)PPPPPPPPPP

Secondary GS1 128 Linear Barcode

Primary GS1 128 Barcode

N(01) 1 03 0019 1323 87 S (30) 20

### RFID Tag Placement Only



Single Dose Container 75 mL NDC 0019-1323-85  
Sterile Solution

## Optiray® 320

**Ioversol Injection 68%**  
320 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only** Rx only Not For Intrathecal Use 

Each mL contains 678 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Medication and fluid pathway are sterile. Outside of syringe is not sterile. Single dose syringe. Discard unused portion and syringe. Protect from light.**

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616  
Made in USA

Guerbet | 

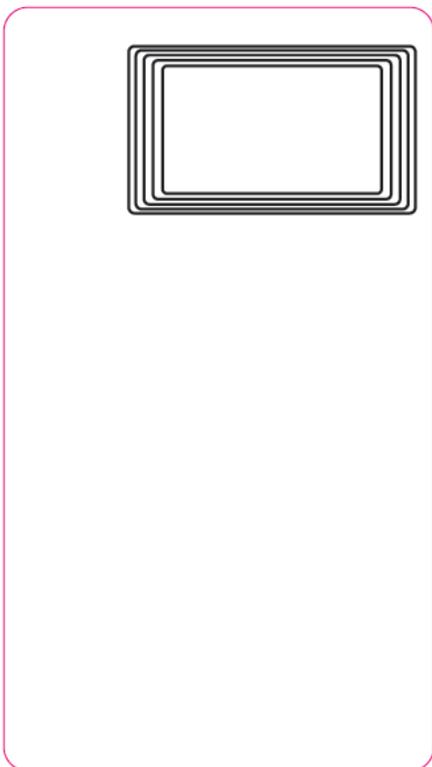
Lot:             
Mfg:             
Exp:           

16371021



3 00191 32385 9

### RFID Tag Placement Only



Single Dose Container  
Sterile Solution 100 mL NDC 0019-1323-00

## Optiray<sup>®</sup> 320

**Ioversol Injection 68%**  
320 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only** Rx only  
Not For Intrathecal Use



Each mL contains 678 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Medication and fluid pathway are sterile. Outside of syringe is not sterile. Single dose syringe. Discard unused portion and syringe. Protect from light.**

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616  
Made in USA

Lot:    
Mfg:    
Exp:  

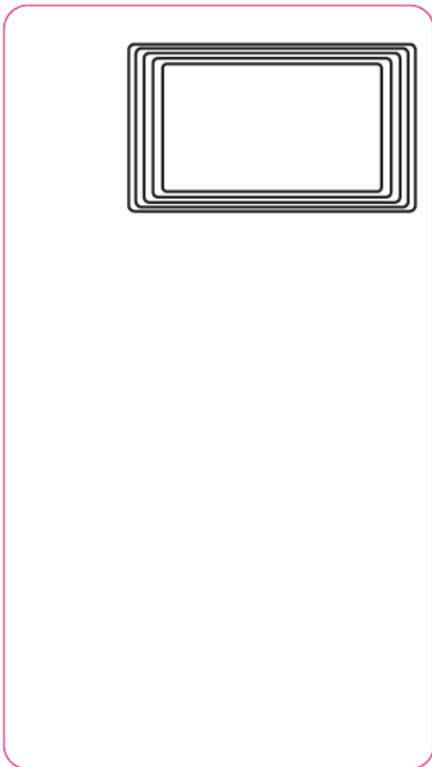
Guerbet | 

16381021



3 00191 32300 2

### RFID Tag Placement Only



Single Dose Container 125 mL NDC 0019-1323-27  
Sterile Solution

## Optiray® 320

**Ioversol Injection 68%**  
320 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only** Rx only Not For Intrathecal Use 

Each mL contains 678 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Medication and fluid pathway are sterile. Outside of syringe is not sterile. Single dose syringe. Discard unused portion and syringe. Protect from light.**

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616  
Made in USA

Guerbet | 

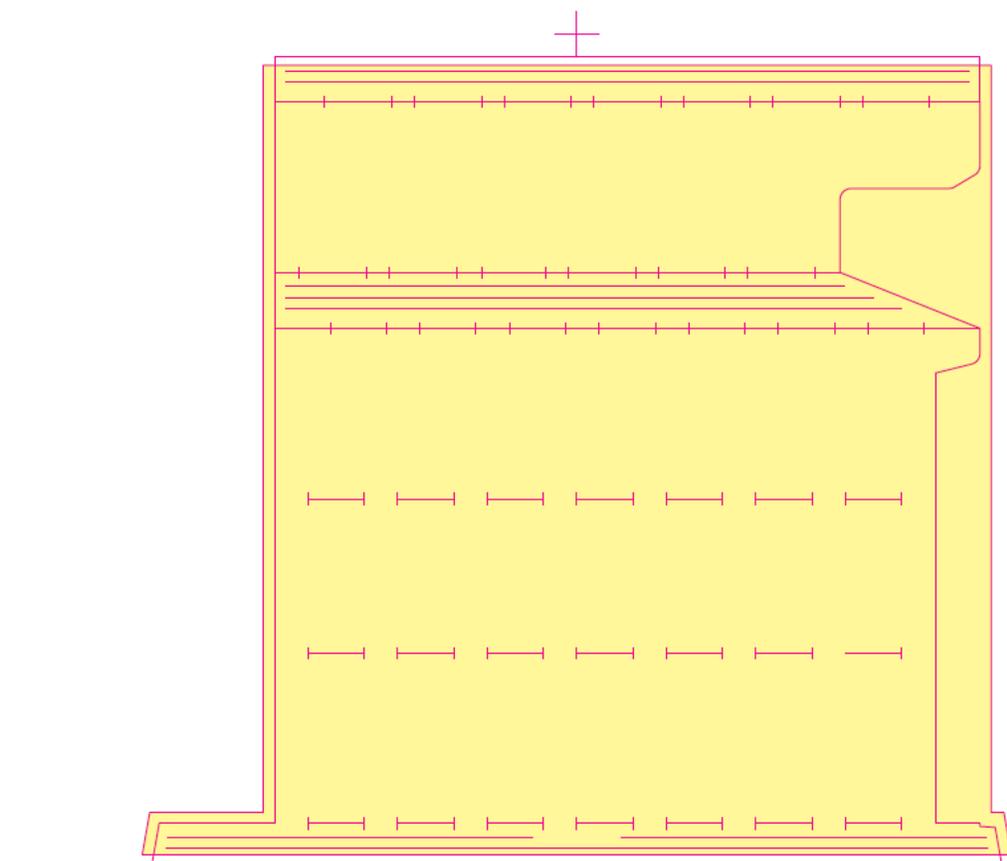
Lot:             
Mfg:             
Exp:           

16391021



3 00191 32327 9

(b) (4)



GUERBET LLC  
3.375 X 1.938 X 9.500 - PRINTSIDE  
S190958 - 10/1/19  
GBT125PI

**Optiray® 320** NDC 0019-1223-85 **75 mL**

**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine

**Rx only**  
**1 syringe**

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

Guerbet |

2385CT R10/21

Push Here  
Then Lift to Open

**Optiray® 320** Single Dose Container Sterile Solution NDC 0019-1323-85 **75 mL**

**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine

**1 syringe** **Rx only**

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

Ultraject®  
PREFILLED SYRINGE  
FOR POWER INJECTION

Guerbet |

2385CT R10/21

Manufactured by:  
Liesbet-Franzheim Company LLC  
Raleigh, NC 27616  
Made in USA

Protect from light • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].  
Do not remove syringe until ready for use.  
Each mL contains 678 mg Ioversol, 3.6 mg bromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.  
**Single dose syringe • Discard unused portion and syringe.**  
Medication and Fluid Pathway are sterile. Outside of syringe is not sterile.  
Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.  
Contains one sterile luer lock nut.  
Recommended Dosage: See Prescribing Information for indications, dosage and dispensing information.

**Optiray® 320** NDC 0019-1223-85 **75 mL**

**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine

**Rx only**  
**1 syringe**

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

Guerbet |

2385CT R10/21

Please Recycle Carton

**Assembly and Inspection**

NOTE: Exterior of syringe is not sterile.  
Contents of syringe and area under tip cap and piston ribs are sterile and should be treated accordingly.

Attach luer lock nut to syringe by holding dust cover and screwing to the stop. Remove and discard dust cover when ready to attach sterile connector tubing.

Next remove cap from luer lock nut. Discard cap by twisting to break tamper evident seal. Discard caps.

To remove tip cap from syringe, push in and twist off, then discard. The area under the cap is sterile. Carton should now be used when handling.

Remove syringe from carton and inspect the area around the tip cap and outside of piston for signs of leakage. Do not use if leakage is observed. Load syringe into power injector.

**Optiray® 320** NDC 0019-1323-85 **75 mL**

**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine

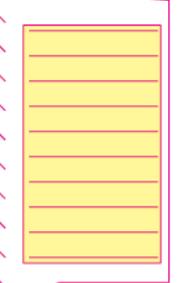
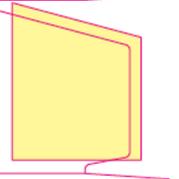
**Rx only**  
**1 syringe**

**For Intravenous and Intra-arterial Use Only**

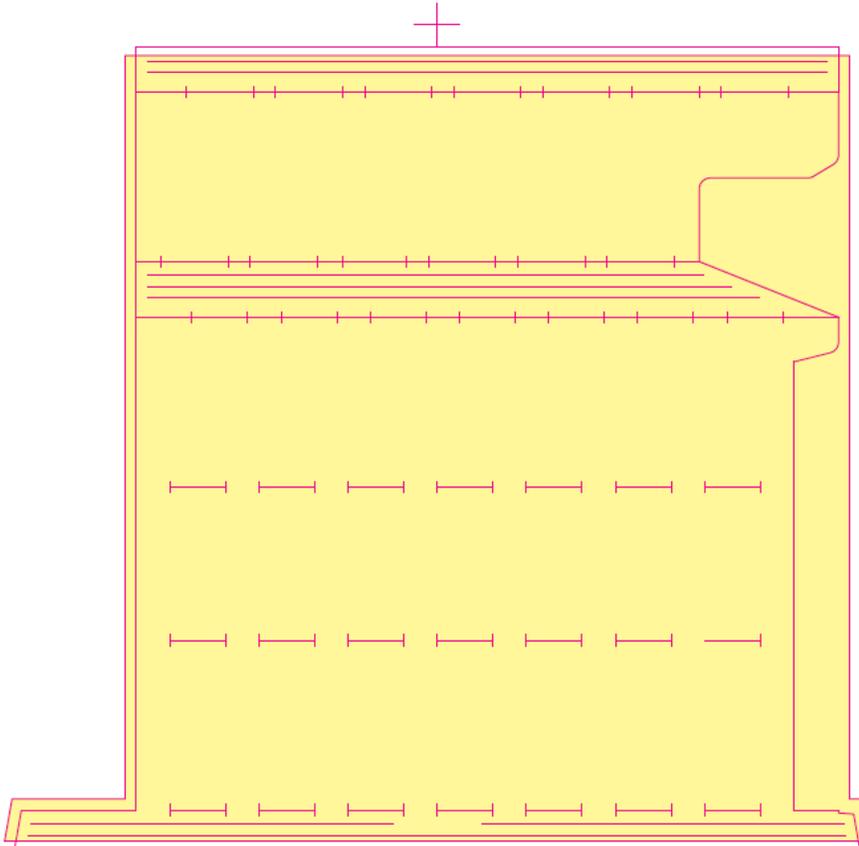
Not For Intrathecal Use

Guerbet |

2385CT R10/21



(b) (4)



GUERBET LLC  
3.375 X 1.938 X 9.500 - PRINTSIDE  
S190958 - 10/1/19  
GBT125PI

2300CT  
R10/21

**Optiray® 320** NDC 0019-1323-00 100 mL  
**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine  
**Rx only**  
**1 syringe**  
**For Intravenous and Intra-arterial Use Only**  
Not For Intrathecal Use  
Guerbet |

Push Here  
Then Lift To Open

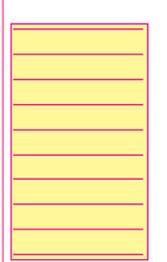


**Optiray® 320** Single Dose Container Sterile Solution NDC 0019-1323-00 100 mL  
**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine  
**1 syringe Rx only**  
**For Intravenous and Intra-arterial Use Only**  
Not For Intrathecal Use  
**Ultraject®** PREFILLED SYRINGE FOR POWER INJECTION   
Manufactured by: Liebel-Flarsheim Company LLC Raleigh, NC 27616 Made in USA  
Guerbet |

**Optiray® 320** 100 mL NDC 0019-1323-00  
**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine  
**Rx only**  
**1 syringe**  
**For Intravenous and Intra-arterial Use Only**  
Not For Intrathecal Use  
Guerbet |

2300CT  
R10/21

**Optiray® 320** NDC 0019-1323-00 100 mL  
**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine  
**Rx only**  
**1 syringe**  
**For Intravenous and Intra-arterial Use Only**  
Not For Intrathecal Use  
Guerbet |



Attach luer lock nut to syringe by holding disc cover and screwing to the stop. Remove and discard disc cover when ready to attach sterile connector tubing.



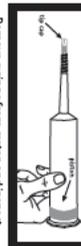
Heat remove cap from luer lock nut disc cover by twisting to break tamper evident seal. Discard cap.



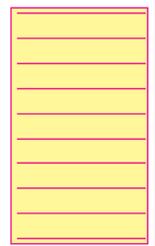
Remove tip cap from syringe, push in and twist off then discard. The area under the cap is sterile. Caution should now be used when handling.



Remove syringe from carton and inspect the area under the tip cap and outside of plunger for signs of leakage. Do not use if leakage is observed. Load syringe into power injector.



**Assembly and Inspection**  
**NOTE:** Exterior of syringe is not sterile. Contents of syringe and area under tip cap and plunger are sterile and should be treated accordingly.



(b) (4)

2327CT  
10/21

### Optiray® 320

NDC 0019-1323-27

125 mL

**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

Guerbet | 

**Rx only**  
**1 syringe**

 **RFID Technology**

Push Here  
Then Lift to Open



### Optiray® 320

Single Dose Container  
Sterile Solution

NDC 0019-1323-27

125 mL

**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine

**1 syringe**

**Rx only**

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

**Ultraject®**  
PREFILLED SYRINGE  
FOR POWER INJECTION

 **RFID Technology**

Protect from light - Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) (see USP Controlled Room Temperature). Do not remove syringe until ready for use.

Each mL contains 6.78 mg Ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

Single dose syringe - Discard unused portion and syringe.

Medication and Fluid Pathway are sterile. Outside of syringe is not sterile. Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed. Contains one sterile luer lock nut.

Recommended Dosage: See Prescribing Information for Indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616  
Made in USA

Guerbet | 

125 mL  
NDC 0019-1323-27

**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine  
**1 syringe**  
**For Intravenous and Intra-arterial Use Only**  
Not For Intrathecal Use

 **RFID Technology**  
Guerbet | 

2327CT  
10/21

### Optiray® 320

NDC 0019-1323-27

125 mL

**IOVERSOL INJECTION 68%**  
320 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

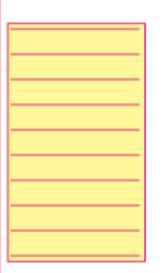
Guerbet | 

**Rx only**  
**1 syringe**

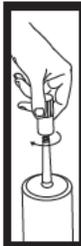
 **RFID Technology**



Please  
Recycle  
Carton



Attach luer lock nut to syringe by holding dust cover and screwing to the stop. Remove and discard dust cover when ready to attach sterile connector tubing.



Remove cap from luer lock nut dust cover by twisting to break tamper evident seal. Discard cap.



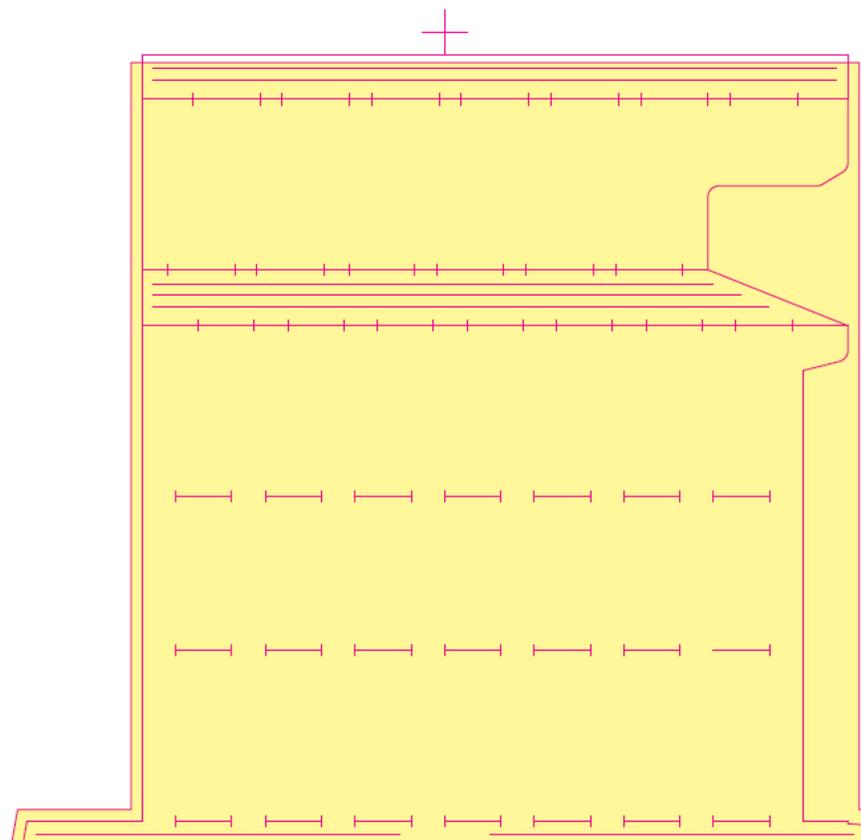
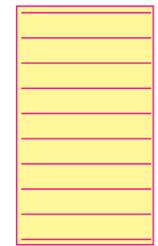
To remove tip cap from syringe, push in and twist off the end cap. The area under the cap is sterile. Cap should now be used when handling.



Remove syringe from carton and inspect the syringe for any damage and outside of piston for signs of leakage. Do not use if leakage is observed. Load syringe into power injector.



**Assembly and Inspection**  
NOTE: Exterior of syringe is not sterile. Contents of syringe and area under tip cap and piston ribs are sterile and should be treated accordingly.



GUERBET LLC  
3.375 X 1.938 X 9.500 - PRINTSIDE  
S190958 - 10/1/19  
GBT125PI

# Optiray® 320

Single Dose Container  
Sterile Solution

1323RFID

**Ioversol Injection 68%**  
320 mg/mL Organically Bound Iodine

**For Intravenous and  
Intra-arterial Use Only**

 **RFID Technology**  
**Ultraject®** **Rx only**  
PREFILLED SYRINGE  
FOR POWER INJECTION

**Guerbet** |   
Not For  
Intrathecal Use

23US90LR0422

**Protect from light** - Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Do not remove syringe until ready for use.

Each mL contains 678 mg Ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Single dose syringe - Discard unused portion and syringe.**

**Medication and Fluid Pathway are sterile. Outside of syringe is not sterile.**

Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information. **Manufactured by:** Liebel-Flarsheim Company LLC, Raleigh, NC 27616 **Made in USA**

For Power Injection

NDC 0019 1323 85

20 x 75mL syringes

QTY: 20

EXP: MM/YYYY

LOT #: P P P P P P P P

(30)20 (17)YYMMDD (10)P P P P P P P P P P

Secondary GS1 128 Linear Barcode

Primary GS1 128 Barcode

N(01) 1 03 0019 1323 85 S (30) 20

# Optiray<sup>®</sup> 320

Single Dose Container  
Sterile Solution

1323RFID

**Ioversol Injection 68%**  
320 mg/mL Organically Bound Iodine

**For Intravenous and  
Intra-arterial Use Only**

 **RFID Technology**  
**Ultraject<sup>®</sup>** **Rx only**  
PREFILLED SYRINGE  
FOR POWER INJECTION  
**Guerbet |**   
Not For  
Intrathecal Use

23US90LR0422

**Protect from light** - Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Do not remove syringe until ready for use.

Each mL contains 678 mg Ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Single dose syringe - Discard unused portion and syringe.**

**Medication and Fluid Pathway are sterile. Outside of syringe is not sterile.**

Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information. **Manufactured by:** Liebel-Flarsheim Company LLC, Raleigh, NC 27616 **Made in USA**

For Power Injection

NDC 0019 1323 00

20 x 100mL syringes

QTY: 20

EXP: MM/YYYY

LOT #: P P P P P P P P

(30)20 (17)YYMMDD (10)P P P P P P P P P P

Secondary GS1 128 Linear Barcode

Primary GS1 128 Barcode

N(01) 1 03 0019 1323 00 S (30) 20

# Optiray® 320

Single Dose Container  
Sterile Solution

1323RFID

**Ioversol Injection 68%**  
320 mg/mL Organically Bound Iodine

**For Intravenous and  
Intra-arterial Use Only**

 **RFID Technology**  
**Ultraject®** **Rx only**  
PREFILLED SYRINGE  
FOR POWER INJECTION  
**Guerbet |**   
Not For  
Intrathecal Use

23US90LR0422

**Protect from light** - Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Do not remove syringe until ready for use.

Each mL contains 678 mg Ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Single dose syringe - Discard unused portion and syringe.**

**Medication and Fluid Pathway are sterile. Outside of syringe is not sterile.**

Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information. **Manufactured by:** Liebel-Flarsheim Company LLC, Raleigh, NC 27616 **Made in USA**

For Power Injection

NDC 0019 1323 27

20 x 125mL syringes

QTY: 20

EXP: MM/YYYY

LOT #: P P P P P P P P

(30)20 (17)YYMMDD (10)P P P P P P P P P P

Secondary GS1 128 Linear Barcode

Primary GS1 128 Barcode

N(01) 1 03 0019 1323 27 S (30) 20

Single-Dose Container Sterile Solution **Optiray® 300** 50 mL NDC 0019-1332-06

Lot: [Redacted]  
Mfg: [Redacted]  
Exp: [Redacted]

**Rx only**  
Not For  
Intrathecal Use

**Optiray® 300** 50 mL NDC 0019-1332-06

**Ioversol Injection 64%**  
300 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only**

**Protect from light** • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Discard contents if product is frozen or if crystallization occurs.  
Each mL contains 636 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer.  
The pH is adjusted with hydrochloric acid or sodium hydroxide.  
**Single dose container • Discard unused portion**  
**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

12551021

Manufactured by:  
Lieber-Franheim Company LLC  
Raleigh, NC 27616  
Made in USA

9 00191 33206 14100

Guerbet | 

05	Lot	Single-Dose Container	<b>Optiray® 300</b>	100 mL	0	
	Mfg	Sterile Solution		NDC 0019-1332-11		75
	Exp					50
57	Rx only Not For Intrathecal Use		<b>Ioversol Injection 64%</b> 300 mg/mL Organically Bound Iodine		3	
100	Guerbet   		<b>For Intravenous and Intra-arterial Use Only</b>		0	
	Manufactured by: Liesel-Flarsheim Company LLC Raleigh, NC 27616 Made in USA		Protect from light • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Discard contents if product is frozen or if crystallization occurs. Each mL contains 636 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide. Single dose container • Discard unused portion Recommended Dosage: See Prescribing Information for indications, dosage and dispensing information.		0	
			<b>Ioversol Injection 64%</b>		1	
			100 mL		3	
			Single-Dose Container		25	
			<b>Optiray® 300</b>			
				12561021		

SZ

125

00L

100

SZL

75

0SL

50

25

Single-Dose Container  
Sterile Solution

# Optiray® 300

150 mL

NDC 0019-1332-16

Lot: XXXXXXXXXX

Mfg: XXXXXXXXXX

Exp: XXXXXXXXXX

**Rx only**  
Not For  
Intrathecal Use

**Guerbet** |

**loversol Injection 64%**  
300 mg/mL Organically Bound Iodine

For Intravenous and Intra-arterial Use Only

**Protect from light** • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Discard contents if product is frozen or if crystallization occurs. Each mL contains 636 mg loversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Single dose container • Discard unused portion**

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

12571021

Manufactured by:  
Lieber-Fleishheim Company LLC  
Raleigh, NC 27616  
Made in USA

NDC 0019-1332-16

150 mL

Single-Dose Container  
Sterile Solution

Optiray® 300

3 0 0 1 9 1 3 3 2 1 6 5

00L  
Single-Dose Container  
Sterile Solution

Optiray® 300

200 mL  
NDC 0019-1332-21

Lot: ██████████

Mfg: ██████████

Exp: ██████████

Ioversol Injection 64%

300 mg/mL Organically Bound Iodine

For Intravenous and Intra-arterial Use Only

**Protect from light** • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Discard contents if product is frozen or if crystallization occurs.  
 Each mL contains 636 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.  
**Single dose container • Discard unused portion**  
**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

200

175

150

125

100

75

50

Guerbet |

12581021

NDC 0019-1332-21

Single-Dose Container  
Sterile Solution

Optiray® 300

200 mL

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616  
Made in USA

3 00191 33221 9

Rx only  
Not For  
Intrathecal Use

(b) (4)

# Optiray® 300

**Ioversol Injection 64%**  
300 mg/mL Organically Bound Iodine

**For Intravenous and  
Intra-arterial Use Only**

Not For Intrathecal Use  
**Rx only**

32USB90L0422

Single-Dose Container  
Sterile Solution

1332BOT

**Protect from light** - Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].  
Discard contents if product is frozen or if crystallization occurs.

**Single dose containers - Discard unused portion**

Each mL contains 636 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer.  
The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Lieber-Farsheim Company LLC  
Raleigh, NC 27616  
Made in USA

**Guerbet** | 

25 x 50 mL bottles

SKU: 133206

EXP: MM/YYYY    LOT: P P P P P P P P    QTY: 25    MFG: MM/YYYY

Linear Barcode

(17)YYMMDD(10)PPPPPPPP(30)XX(11)YYMMDD

NDC 0019-1332-06

GTIN-14 Barcode



(b) (4)

# Optiray® 300

**Ioversol Injection 64%**  
300 mg/mL Organically Bound Iodine

**For Intravenous and  
Intra-arterial Use Only**

Not For Intrathecal Use  
**Rx only**

32USB90L0422

Single-Dose Container  
Sterile Solution

1332BOT

**Protect from light** - Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].  
Discard contents if product is frozen or if crystallization occurs.

**Single dose containers - Discard unused portion**  
Each mL contains 636 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer.  
The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Lieber-Farsheim Company LLC  
Raleigh, NC 27616  
Made in USA

**Guerbet** |

12 x 100 mL bottles

SKU: 133211

EXP: MM/YYYY    LOT: P P P P P P P P    QTY: 12    MFG: MM/YYYY

Linear Barcode

(17)YYMMDD(10)PPPPPPPP(30)XX(11)YYMMDD

NDC 0019-1332-11

GTIN-14 Barcode

# Optiray® 300

**Ioversol Injection 64%**  
300 mg/mL Organically Bound Iodine

**For Intravenous and  
Intra-arterial Use Only**

Not For Intrathecal Use  
**Rx only**

32USB90L0422

Single-Dose Container  
Sterile Solution

1332BOT

**Protect from light** - Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].  
Discard contents if product is frozen or if crystallization occurs.

**Single dose containers - Discard unused portion**

Each mL contains 636 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer.  
The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Lieber-Farsheim Company LLC  
Raleigh, NC 27616  
Made in USA

**Guerbet** | 

12 x 150 mL bottles

SKU: 133216

EXP: MM/YYYY    LOT: P P P P P P P P    QTY: 12    MFG: MM/YYYY

Linear Barcode

(17)YYMMDD(10)PPPPPPPP(30)XX(11)YYMMDD

NDC 0019-1332-16

GTIN-14 Barcode

(b) (4)

# Optiray® 300

**Ioversol Injection 64%**  
300 mg/mL Organically Bound Iodine

**For Intravenous and  
Intra-arterial Use Only**

Not For Intrathecal Use  
**Rx only**

32USB90L0422

Single-Dose Container  
Sterile Solution

1332BOT

**Protect from light** - Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].  
Discard contents if product is frozen or if crystallization occurs.

**Single dose containers - Discard unused portion**

Each mL contains 636 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer.  
The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616  
Made in USA

**Guerbet** | 

12 x 200 mL bottles

SKU: 133221

EXP: MM/YYYY    LOT: P P P P P P P P    QTY: 12    MFG: MM/YYYY

Linear Barcode

(17)YYMMDD(10)PPPPPPPP(30)XX(11)YYMMDD

NDC 0019-1332-21

GTIN-14 Barcode

Single Dose Container  
Sterile Solution

100 mL  
NDC 0019-1332-90

# Optiray<sup>®</sup> 300

**Ioversol Injection 64%**  
300 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only**

**Rx only**

Not For Intrathecal Use

**Medication and fluid pathway are sterile. Outside of syringe is not sterile. Single dose syringe • Discard unused portion and syringe.**

**Protect from light** • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Each mL contains 636 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide. Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616 Made in USA

Guerbet | 



Lot:  
Mfg:  
Exp:

15-441021

(b) (4)

3290CT  
R10/21

Lot:  
Mfg/Exp:



### Optiray<sup>®</sup> 300

NDC 0019-1332-90 100 mL

#### IOVERSOL INJECTION 64%

300 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

Rx only

1 syringe

Guerbet |

Push Here  
Then Lift to Open

### Optiray<sup>®</sup> 300

Single Dose Container  
Sterile Solution

NDC 0019-1332-90 100 mL

#### IOVERSOL INJECTION 64%

300 mg/mL Organically Bound Iodine

1 syringe Rx only

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

**Ultraject<sup>®</sup>**  
PREFILLED SYRINGE  
FOR POWER INJECTION

Protect from light • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Do not remove syringe until ready for use.  
Each mL contains 636 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.  
Single dose syringe • Discard unused portion and syringe.  
Medication and Fluid Pathway are sterile. Outside of syringe is not sterile.  
Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.  
Contains one sterile luer lock nut.  
Recommended Dosage: See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616  
Made in USA

Guerbet |

100 mL  
IOVERSOL INJECTION 64%  
300 mg/mL Organically Bound Iodine  
Rx only  
1 syringe  
Guerbet |

**For Intravenous and Intra-arterial Use Only**  
Not For Intrathecal Use  
3290CT  
R10/21

3290CT  
R10/21

### Optiray<sup>®</sup> 300

NDC 0019-1332-90 100 mL

#### IOVERSOL INJECTION 64%

300 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

Rx only

1 syringe

Guerbet |



Please  
Recycle  
Carton

Attach luer lock nut to syringe by holding dust cover and screwing to the stop. Remove and discard dust cover when ready to attach sterile connector tubing.



Heat remove cap from luer lock nut dust cover by twisting to break tamper evident seal. Discard cap.



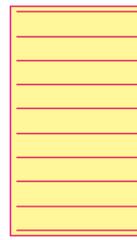
To remove tip cap from syringe, push in and twist off, then discard. The area under the cap is sterile. Cartons should now be used when handling.



Remove syringe from carton and inspect the syringe for any damage or leakage of piston or signs of leakage. Do not use if leakage is observed. Load syringe into power injector.



**Assembly and Inspection**  
NOTE: Exterior of syringe is not sterile. Contents of syringe and area under tip cap and piston flaps are sterile and should be treated accordingly.



GUERBET LLC  
3.375 X 1.938 X 9.500 - PRINTSIDE  
S190958 - 10/1/19  
GBT125PI

# Optiray<sup>®</sup> 300

Single Dose Container  
Sterile Solution

1332SYR

**Ioversol Injection 64%**  
300 mg/mL Organically Bound Iodine

**For Intravenous and  
Intra-arterial Use Only**

14210422

Guerbet | 

**Ultraject<sup>®</sup>**  
PREFILLED SYRINGE

**Rx only**  
Not For  
Intrathecal Use

**Protect from light** - Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Do not remove syringe until ready for use.

Each mL contains 636 mg Ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Single dose syringe - Discard unused portion and syringe. Medication and Fluid Pathway are sterile. Outside of syringe is not sterile.**

Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information. **Manufactured by:** Liebel-Farshem Company LLC, Raleigh, NC 27616 Made in USA

For Power Injection

NDC 0019 1332 90

20 x 100mL syringes

QTY: 20

EXP: MM/YYYY

LOT #: PPPPPPP

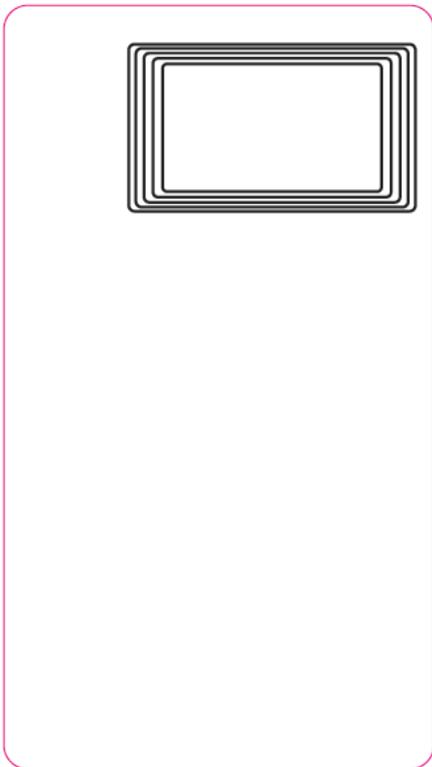
(30)20 (17)YYMMDD (10)PPPPPPPPPP

Secondary GS1 128 Linear Barcode

Primary GS1 128 Barcode

N(01) 1 03 0019 1332 90 S (30) 20

### RFID Tag Placement Only



Single Dose Container 100 mL NDC 0019-1332-00  
Sterile Solution

## Optiray® 300

Ioversol Injection 64%  
300 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only**    **Rx only**  
Not For Intrathecal Use    **RFID Technology**

Each mL contains 636 mg ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Medication and fluid pathway are sterile. Outside of syringe is not sterile. Single dose syringe. Discard unused portion and syringe. Protect from light.**

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616  
Made in USA

Lot:             
Mfg:             
Exp:           

Guerbet |

16401021

3 00191 33200 4

(b) (4)

3200CT  
R10/21

**Optiray® 300** NDC 0019-1332-00 100 mL

**IOVERSOL INJECTION 64%**

300 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

Guerbet | 

Rx only  
1 syringe



Push Here  
Then Lift to Open



**Optiray® 300** Single Dose Container Sterile Solution NDC 0019-1332-00 100 mL

**IOVERSOL INJECTION 64%**

300 mg/mL Organically Bound Iodine

**1 syringe Rx only**

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

**Ultraject®**  
PREFILLED SYRINGE  
FOR POWER INJECTION



**Protect from light** - Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].  
Do not remove syringe until ready for use.  
Each mL contains 636 mg Ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.  
**Single dose syringe - Discard unused portion and syringe.**  
**Medication and Fluid Pathway are sterile. Outside of syringe is not sterile.**  
Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed. Contains one sterile luer lock nut.  
**Recommended Dosage:** See Prescribing Information for Indications, dosage and dispensing information.

Manufactured by:  
Liebel-Flarsheim Company LLC  
Raleigh, NC 27616  
Made in USA

Guerbet | 

**Optiray® 300** 100 mL  
NDC 0019-1332-00  
**IOVERSOL INJECTION 64%**  
300 mg/mL Organically Bound Iodine  
**Rx only**  
**1 syringe**  
**For Intravenous and Intra-arterial Use Only**  
Not For Intrathecal Use  
RFID Technology  
Guerbet |   
ASSET TRACK

3200CT  
R10/21

**Optiray® 300** NDC 0019-1332-00 100 mL

**IOVERSOL INJECTION 64%**

300 mg/mL Organically Bound Iodine

**For Intravenous and Intra-arterial Use Only**

Not For Intrathecal Use

Guerbet | 

Rx only  
1 syringe



Please  
Recycle  
Carton

Attach luer lock nut to syringe by holding dust cover and screwing to the stop. Remove and discard dust cover when ready to attach sterile connector tubing.



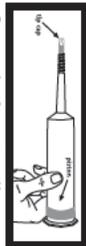
Next remove cap from luer lock, not dust cover by twisting to break tamper evident seal. Discard cap.



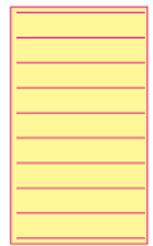
To remove lip cap from syringe, push in and twist cap then discard. The area under the cap is sterile. Caution should now be used when handling.



Remove syringe from carton and inspect the area around the lip cap and outside of piston for signs of leakage. Do not use if leakage is observed. Load syringe into power injector.



**Assembly and Inspection**  
**NOTE:** Exterior of syringe is not sterile. Contents of syringe and area under lip cap and piston are sterile and should be treated accordingly.



GUERBET LLC  
3.375 X 1.938 X 9.500 - PRINTSIDE  
S190958 - 10/1/19  
GBT125PI

# Optiray<sup>®</sup> 300

Single Dose Container  
Sterile Solution

1332RFID

**Ioversol Injection 64%**  
300 mg/mL Organically Bound Iodine

**For Intravenous and  
Intra-arterial Use Only**

 **RFID Technology**  
**Ultraject<sup>®</sup>** **Rx only**  
PREFILLED SYRINGE **Not For**  
FOR POWER INJECTION **Intrathecal Use**

 **Guerbet**  
32015901.R0422

**Protect from light** • Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Do not remove syringe until ready for use.

Each mL contains 636 mg Ioversol, 3.6 mg tromethamine as a buffer and 0.2 mg edetate calcium disodium as a stabilizer. The pH is adjusted with hydrochloric acid or sodium hydroxide.

**Single dose syringe • Discard unused portion and syringe.**

**Medication and Fluid Pathway are sterile. Outside of syringe is not sterile.**

Discard contents if syringe is frozen, if crystallization occurs, syringe seal is broken or if leaking is observed.

**Recommended Dosage:** See Prescribing Information for indications, dosage and dispensing information. **Manufactured by:** Liebel-Flarsheim Company LLC, Raleigh, NC 27616 **Made in USA**

For Power Injection

NDC 0019 1332 00                      20 x 100mL syringes

QTY: 20            EXP: MM/YYYY            LOT #: P P P P P P P P

(30)20 (17)YYMMDD (10)P P P P P P P P P P

Secondary GS1 128 Linear Barcode

Primary GS1 128 Barcode

N(01) 1 03 0019 1332 00 S (30) 20

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**  
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/s/  
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LIBERO L MARZELLA  
05/04/2022 07:14:49 PM