US FDA Approves Guerbet's Optiray® (Ioversol Injection) Imaging Bulk Package

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Guerbet LLC USA →
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PRINCETON, N.J., Dec. 3, 2020 /PRNewswire/ -- Guerbet (GBT), a global leader in medical imaging, announced today that it received US Food and Drug Administration approval for the commercial sale of the Optiray® Imaging Bulk Package (IBP) in the United States, as well as FDA clearance of the LF IBP Transfer Set.

Guerbet's Optiray IBP has the capability to fill sterile single-use syringes when used with a power injector and a cleared contrast media transfer set, Guerbet's Optiray IBP presentation is an efficient option because it can reduce the number of single dose vials opened without requiring preparation in a laminar flow hood or pharmacy facility.

The Optiray IBP will be available in 500mL bottles in 2021 for the Optiray 320 and Optiray 350 concentrations

"Guerbet's new Optiray IBP offers our customers the flexibility they seek in the CT suite, with a labeled maximum use time of 12 hours once pierced – presently the longest among iodinated contrast IBPs available in the US. Our innovative product portfolio continues to provide efficient solutions for healthcare providers and their patients," said Thomas McLaughlin, VP, Guerbet North America.

Customers with questions are encouraged to contact Guerbet's Customer Service Department via phone at (877) 729-6679, or via email at customer.service-us@guerbet.com

Important Safety Information[1]

WARNING: RISKS WITH INADVERTENT INTRATHECAL ADMINISTATION

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.

INDICATIONS AND USAGE

Intra-arterial use 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

Intra-arterial use in pediatric patients

- Optiray 320 and Optiray 350: angiocardiography

Intra-venous use 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)

Intra-venous use in pediatric patients

- Optiray 320: CT imaging of the head and body, and intravenous excretory urography

Contraindications

Optiray is contraindicated in patients with symptomatic hyperthyroidism.

Warnings and Precautions

- Optiray can cause life-threatening or fatal hypersensitivity reactions including anaphylaxis and anaphylactic shock.
- 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.
- Acute kidney injury, including renal failure, may occur after Optiray administration.
- 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.
- Cardiac decompensation, serious arrhythmias, and myocardial ischemia or infarction can occur during coronary arteriography and ventriculography.
- Serious, fatal, thromboembolic events causing myocardial infarction and stroke can occur during angiographic procedures with Optiray.
- Extravasation can occur with Optiray administration, particularly in patients with severe arterial or venous disease and can be associated with pain, hemorrhage and necrosis.
- Thyroid storm has occurred following the intravascular use of iodinated radiopaque agents in patients with hyperthyroidism or with an autonomously functioning thyroid nodule.
- Hypertensive crisis has occurred after the use of iodinated radiopaque contrast agents in patient with pheochromocytoma.
- Iodinated contrast agents may promote sickling in individuals who are homozygous for sickle cell disease.
- 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.

Adverse Reactions

- The most common reaction in adults is nausea, occurring at a rate of 1 percent.
- In pediatric patients, adverse reactions reported were similar in quality and frequency to the adverse events reported by adults.
- The following adverse reactions have been reported during post-approval use of Optiray. These adverse reactions include but are not limited to: fatal anaphylactic shock, coronary artery spasm, arrhythmia, temporary blindness, tongue edema, seizures, respiratory arrest, bronchospasm, laryngeal spasm and obstruction, and thrombosis.

Use in Specific Populations

- Pregnancy: Postmarketing data with Optiray use in pregnant women are insufficient to determine if there is a risk of drug-associated adverse developmental outcomes.
- Lactation: 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.
- Pediatric Use: Safety and effectiveness in pediatric patients have been established for the use of Optiray 350 and Optiray 320 in angiocardiography; and for Optiray 320 in computed tomographic imaging of the head and body, and intravenous excretory urography. Safety and effectiveness of Optiray 350 and Optiray 320 have not been established in pediatric patients less than 1 month of age. Safety and effectiveness of Optiray 300 has not been established in pediatric patients.
- Geriatric Use: Optiray is substantially excreted by the kidney, and the risk of adverse reactions to Optiray may be greater in patients with impaired renal function.

You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

References

[1] OptiRay Imaging Bulk Pack [package insert]. Raleigh, NC: Liebel-Flarsheim Company LLC; Nov 2020

About Guerbet

Guerbet is a leader in medical imaging worldwide, offering a wide range of pharmaceutical products, medical devices, digital and AI solutions for diagnostic and interventional imaging, to improve the diagnosis and treatment of patients. A pioneer since more than 90 years in the field of contrast media with over 2,800 people globally, Guerbet is continuously innovating with 9% of revenue dedicated to Research & Development and four centers in France, Israel and the United States. Guerbet (GBT) is listed on Euronext Paris (segment B – mid caps) and generated €817 million in revenue in 2019. For more information about Guerbet, please visit www.guerbet.com.

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