

Drug Shortage: Iohexol (Omnipaque) and Iodixanol (Visipaque)

This document provides mitigation strategies for handling ongoing drug shortages to participants in the Vizient® Pharmacy Program. Information is compiled from mitigation strategies of institutions that serve on the Vizient Clinical Pharmacy Council and is reviewed by a panel of pharmacists. For more information, contact pharmacyquestions@vizientinc.com

Situation

This mitigation strategy is to serve as a resource if Iohexol (Omnipaque) and/or Iodixanol (Visipaque) experience supply disruptions due to shortages.

Background

According to [communication from GE Healthcare](#), a shortage of Iohexol (Omnipaque) is occurring as a result of the Chinese government lockdowns related to COVID-19. Secondarily to the Iohexol (Omnipaque) shortage, the alternative agent, Iodixanol (Visipaque), is in short supply due to an increase in demand.

At the recommendation of GE Healthcare, distributors have implemented a 20% allocation on Iohexol (Omnipaque) that is expected to continue through the remainder of this shortage. Nearly all of the U.S. supply for this product comes from the Shanghai plant. According to GE Healthcare, the supply impact is not related to quality, raw material supply, or supply chain issues. GE Healthcare will utilize their secondary manufacturing facility in Ireland to supplement U.S. labeled Iohexol (Omnipaque) supply. Additionally, GE Healthcare has communicated that the impact is temporary, and the Shanghai facility is re-opened and ramping up production as allowed by local COVID-19 mitigation protocols.

Total global production of iodine, excluding U.S. production data, was estimated at 32,000 metric tons in 2021 which is equivalent to pre-pandemic levels. GE Healthcare expects to have intermittent supply of Iohexol (Omnipaque) until the end of June 2022 and does not have additional information on Iodixanol (Visipaque) availability at this time. This mitigation strategy is intended to provide guidance for present and future shortages.

Products affected^a

Omnipaque 140	<ul style="list-style-type: none"> 140 mg iodine/mL, 50 mL polymer bottle
Omnipaque 180	<ul style="list-style-type: none"> 180 mg iodine/mL, 10, 20 mL vials
Omnipaque 240	<ul style="list-style-type: none"> 240 mg iodine/mL, 10, 20 mL vials 240 mg iodine/mL, 50, 100, 150, 200 mL polymer bottles
Omnipaque 300	<ul style="list-style-type: none"> 300 mg iodine/mL, 10, 125 mL vials 300 mg iodine/mL, 30, 50, 75, 100, 125, 150, 200 mL 300 mg iodine/mL, 500 mL polymer bottles (pharmacy and imaging bulk)
Omnipaque 350	<ul style="list-style-type: none"> 350 mg iodine/mL, 125 mL vials 350 mg iodine/mL, 50, 75, 100, 125, 150, 200 mL 350 mg iodine/mL, 500 mL polymer bottles (pharmacy and imaging bulk)
Omnipaque Oral solution 9	<ul style="list-style-type: none"> 9 mg iodine/mL, 500 mL polymer bottle
Omnipaque Oral solution 12	<ul style="list-style-type: none"> 12 mg iodine/mL, 500 mL polymer bottle
Visipaque 270	<ul style="list-style-type: none"> 270 mg iodine/mL, 50, 100, 150, 200 mL polymer bottles 270 mg iodine/mL, 500 mL polymer bottle (pharmacy bulk)
Visipaque 320	<ul style="list-style-type: none"> 320 mg iodine/mL, 50, 100, 150, 200 mL polymer bottles 320 mg iodine/mL, 500 mL polymer bottle (pharmacy bulk)

^a Review [ASHP Drug Shortages](#) for the most current information

Assessment

Iohexol (Omnipaque) is an iodinated contrast media, specifically a low-osmolality contrast media (LOCM). Iodixanol (Visipaque) is an iso-molar contrast media (IOCM). Both are utilized in computed tomography (CT) scans, X-rays, interventional radiology, and the cardiac catheterization lab. Other FDA-approved LOCMs on the market include iopamidol (Isovue), iopromide (Ultravist), and ioversol (Optiray). Iopromide (Ultravist) and ioversol (Optiray) are manufactured by Bayer and Guerbet, respectively, and account for approximately $\leq 5\%$ of the market share combined. Iopamidol (Isovue), manufactured by Bracco Diagnostics, accounts for the second largest national market share at $\sim 45\%$. Bayer, Guerbet, or Bracco Diagnostics have communicated that they are currently not able to take on new accounts. Iohexol (Omnipaque) and iodixanol (Visipaque), manufactured by GE Healthcare, account for the largest market share at $> 50\%$. These contrast agents are necessary for imaging studies to determine the appropriate diagnosis and subsequent treatment of patients for a variety of disease states. Hospitals and health systems are advised to have a mitigation strategy available, to conserve inventory, in the event of a shortage of these contrast agents. Refer to additional national guidance publications found in [Appendix 1](#) for additional information.

Recommendation

Must know information

- Reschedule non-emergent imaging studies or interventional studies which require iohexol (Omnipaque), iodixanol (Visipaque), or other LOCM agents to conserve available inventory.
- Reserve iohexol (Omnipaque) and iodixanol (Visipaque) for critically ill patients requiring CT studies or cardiac catheterization lab interventions.
- If clinically appropriate, in coordination with radiologists, utilize other imaging study modalities such as magnetic resonance imaging (MRI), ultrasound, or nuclear studies.
- For oral administration, diatrizoate meglumine sodium (Gastrografin) or diatrizoate meglumine sodium (MD-Gastroview) can be utilized as alternatives. For genitourinary administration, alternatives may include diatrizoate (Cystografin), iothalate (Cysto-Conray II), or iothalate (Conray 43).

Clinical

- 1) Reserve iohexol (Omnipaque) and iodixanol (Visipaque) for critically ill patients requiring CT and interventional studies, or cardiac catheterization lab interventions.
 - Determine which patients qualify as critically ill with input from the appropriate hospital and pharmacy leadership bodies, in coordination with radiologists.
 - If clinically appropriate, in coordination with radiologists, utilize other imaging study modalities such as magnetic resonance imaging (MRI), ultrasound, or nuclear studies.
 - To determine if alternative studies are appropriate, please refer to the [American College of Radiology \(ACR\) Appropriateness Criteria guidelines](#) (Scroll down to the AC Portal and use the “Explore by scenario” icon.)
- 2) If utilizing iodixanol (Visipaque) in the catheterization lab, consider reserving for patients with renal insufficiency or cardiac issues.
- 3) Use alternatives to nonionic contrast for oral, rectal, and genitourinary administration. For oral administration, diatrizoate meglumine sodium (Gastrografin) or diatrizoate meglumine sodium (MD-Gastroview) can be utilized as alternatives. For genitourinary administration, alternatives may include diatrizoate (Cystografin), iothalate (Cysto-Conray II), or iothalate (Conray 43).

Operational

- 1) Implement electronic health record changes to notify the ordering provider of the iohexol (Omnipaque) and (iodixanol) Visipaque shortage, provide an option to complete the imaging study without contrast (as clinically appropriate), and provide an option to defer the decision of contrast usage to the radiologists.
- 2) Pull available stock to inpatient pharmacy for inventory control, as able with imaging needs.
- 3) If inventory becomes critically low, reschedule non-emergent imaging or interventional studies which require iohexol (Omnipaque), iodixanol (Visipaque), or other LOCM agents to conserve available inventory.
- 4) Consider implementing strategies to reduce contrast dose and/or minimize waste. Strategies may include:
 - Utilize weight-based dosing (vs. fixed dosing) for CT and aliquot to avoid waste.
 - Reduce contrast dose in conjunction with low kVp protocols that improve contrast conspicuity.
 - Reduce dose and acquire studies with dual-energy protocols (where available) that improve contrast conspicuity.
 - Repackage commercially available containers per FDA guidance or USP Chapter <797> (as applicable to the situation). Refer to [Appendix 2](#) for repackaging considerations.
- 5) Coordinate direct orders with local GE Healthcare representatives.
 - Provide GE Healthcare with current days on-hand of inventory and the quantity needed to provide care for critically ill patients when ordering.
 - GE Healthcare has indicated that health systems sharing this level of transparency will allow for optimization of the allocation process to prioritize immediate needs and bi-weekly requirements for critically ill patients.

Advocacy

Vizient regularly engages with the FDA and other federal agencies and policymakers as appropriate, to communicate the various supply chain challenges that our members are facing. The challenges Vizient members are facing regarding the Contrast Media category have been a high priority in recent FDA meetings with information continually being communicated.

Further Information

- Product availability questions can be directed to GE Healthcare Customer Service (800-292-8514 or ci.weborders@ge.com).
- If challenges working with local representatives, contact Steve Hines, GE national account manager (303-489-0638 or steven.hines@ge.com).
- Questions regarding information outside of the package insert can be directed to GE Medical Affairs (800-654-0118 or medical.affairs@ge.com).
- For more information, contact pharmacyquestions@vizientinc.com.

Appendix 1. National published guidance

Organization	Title
American College of Radiology (ACR)	Statement from the ACR Committee on Drugs and Contrast Media
American College of Radiology (ACR)	ACR Manual on Contrast Media
American Society of Health System Pharmacists (ASHP)	Considerations for Imaging Contrast Shortage Management and Conservation

Appendix 2. Considerations for repackaging^a

Product	Single dose vial (SDV) or bottle	Pharmacy bulk packages	Imaging bulk packages
Iohexol (Omnipaque)	<p>Note: SDVs should be used for a single patient. If a SDV must be used for more than a single patient, organizations must follow USP Chapter <797> Pharmaceutical Compounding – Sterile Preparations.</p> <ul style="list-style-type: none"> Per PI, no “in-use” time listed other than a 4-h limit for use with automated contrast injection system or contrast management system. With no “in-use” time, BUD assignment is based on USP Chapter <797>. Repackaging is considered medium risk compounding under the current version of USP Chapter <797>. The maximum BUD for medium-risk compounding repackaged in a fully compliant pharmacy cleanroom is 30 h. Ensure storage of repackaged product is at a suitable temperature and in a compatible container. 	<ul style="list-style-type: none"> Per PI, “in-use” time of 8 h. In-use time is defined as the “time within which the opened product is to be used.” FDA repackaging guidance states BUD of a repackaged product may not exceed in-use time in PI. 	
Iodixanol (Visipaque)	<ul style="list-style-type: none"> Per PI, no “in-use” time listed. Will be the same as Omnipaque specifications above, but these are single-dose bottles not vials. 	<ul style="list-style-type: none"> Per PI, “in-use” time of 8 h. In-use time is defined as the “time within which the opened product is to be used.” FDA repackaging guidance states BUD of a repackaged product may not exceed in-use time listed in PI. 	n/a

Abbreviations: BUD = beyond use dating; PI = product labeling

^a For additional considerations, please refer to ASHP’s [Considerations for Imaging Contrast Shortage Management and Conservation](#)

References

- U.S. Geological Survey, 2022, Mineral commodity summaries 2022: U.S. Geological Survey, 202 p. Accessed May 10, 2022
- Omnipaque [package insert]. Marlborough, MA: GE Healthcare; 2019.
- Visipaque [package insert]. Marlborough, MA: GE Healthcare; 2020.
- Isovue [package insert]. Monroe Township, NJ: Bracco Diagnostics; 2022.
- Ultravist [package insert]. Wayne, NJ: Bayer Healthcare Pharmaceuticals; 2022.
- Optiray [package insert]. Raleigh, NC: Guerbet; 2020.
- MD-Gastroview [package insert]. Raleigh, NC: Guerbet; 2021.
- Gastrografin [package insert]. Monroe Township, NJ: Bracco Diagnostics; 2021.
- ACR Committee on Drugs and Contrast Media. ACR Manual on Contrast Media, 2021. Reston, VA: American College of Radiology; 2021.
- United States Pharmacopeia (USP-797). United States Pharmacopeial Convention; 2021. Accessed May 3, 2022.

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