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Channel:                      Devices, Pharmaceutical      FDA:                      Not Specified      Last Updated: 05/23/2022

**Production Disruption of GE Healthcare Omnipaque (Iohexol) and Visipaque (Iodixonal) Could Impact Imaging Studies, Causing Delays or Cancellations**

**Product Identifier(s)**

[Consumable]

Product	GE Healthcare NDC
270 mg/1 mL, INJECTION, SOLUTION, IV	0407-2222-23
	0407-2222-24
	0407-2222-02
	0407-2222-03
	0407-2222-16
	0407-2222-17
	0407-2222-21
	0407-2222-50
	0407-2222-52
	0407-2222-53
	0407-2222-54
0407-2222-55	
320 mg/1 mL, INJECTION, SOLUTION, IV	0407-2223-23
	66318-223-23
	0407-2223-61
	0407-2223-64
	0407-2223-55
0407-2223-57	
320 mg/1 mL, INJECTION, SOLUTION, IV	0407-2223-58
	66318-223-58
	0407-2223-60
	0407-2223-62

	0407-2223-63
	0407-2223-65
	0407-2223-66
	0407-2223-67
	0407-2223-01
	0407-2223-02
	0407-2223-03
	0407-2223-16
	0407-2223-17
	0407-2223-19
	0407-2223-21
	0407-2223-50
	0407-2223-51
	0407-2223-53
	0407-2223-54
	0407-2223-56
270 mg/1 mL, INJECTION, SOLUTION, IV	0407-2222-01
	0407-2222-06
	0407-2222-19
320 mg/1 mL, INJECTION, SOLUTION	0407-2223-04
	0407-2223-06
300 mg/1 mL, INJECTION, SOLUTION, IV	0407-1413-68
300 mg/1 mL, INJECTION, SOLUTION, IV	0407-1413-94
	0407-1413-72
	0407-1413-89
	0407-1413-48
	0407-1413-10
	0407-1413-11
	0407-1413-30

	0407-1413-50
	0407-1413-51
	0407-1413-53
	0407-1413-59
	0407-1413-60
	0407-1413-61
	0407-1413-62
	0407-1413-63
	0407-1413-65
	0407-1413-69
	0407-1413-90
	0407-1413-91
	0407-1413-92
	0407-1413-93
	0407-1413-95
	0407-1413-96
	0407-1413-98
	0407-1413-99
350 mg/1 mL, INJECTION, SOLUTION, IV	0407-1414-25
	0407-1414-98
	0407-1414-88
	0407-1414-48
	0407-1414-03
	0407-1414-04
	0407-1414-20
	0407-1414-21
	0407-1414-22
	0407-1414-23
	0407-1414-24

	0407-1414-51
	0407-1414-52
	0407-1414-53
	0407-1414-60
	0407-1414-76
	0407-1414-80
	0407-1414-89
	0407-1414-91
	0407-1414-93
	0407-1414-94
	0407-1414-95
	0407-1414-41
	0407-1414-42
	0407-1414-43
	0407-1414-44
	0407-1414-45
	0407-1414-82
	0407-1414-84
	0407-1414-85
	0407-1414-86
	0407-1414-87
350 mg/1 mL INJECTION, SOLUTION, IV	0407-1414-72
9 mg/1 mL, SOLUTION, ORAL	0407-1415-09
12 mg/1 mL, SOLUTION, ORAL	0407-1416-12
388.3 mg/1 mL, SOLUTION, IV	42852-014-10
388.3 mg/1 mL, SOLUTION, IV	42852-014-12
388.3 mg/1 mL, SOLUTION, IV	42852-014-15
518 mg/1 mL, SOLUTION, IV	42852-017-10
	42852-017-12

518 mg/1 mL, SOLUTION, IV	42852-017-15
647.1 mg/1 mL, SOLUTION, IV	42852-020-10
	42852-020-12
	42852-020-15
240 mg/1 mL, INJECTION, SOLUTION, IV	0407-1412-10
	0407-1412-20
	0407-1412-27
	0407-1412-28
	0407-1412-29
	0407-1412-33
	0407-1412-34
	0407-1412-35
	0407-1412-49
	0407-1412-50
240 mg/1 mL, INJECTION, SOLUTION, IV	0407-1412-30
	0407-1412-60
300 mg/1 mL, INJECTION, SOLUTION, IV	0407-1413-66
350 mg/1 mL, INJECTION, SOLUTION, IV	0407-1414-50
	0407-1414-90
140 mg/1 mL, INJECTION, SOLUTION, IV	0407-1401-52
180 mg/1 mL, INJECTION, SOLUTION, ORAL	0407-1411-10
	0407-1411-20
240 mg/1 mL, INJECTION, SOLUTION, IT	0407-1412-38
240 mg/1 mL, INJECTION, SOLUTION, IT	0407-1412-39
	0407-1412-40
	0407-1412-84
300 mg/1 mL, INJECTION, SOLUTION, IT	0407-1413-41
	0407-1413-42
	0407-1413-43

0407-1413-46
0407-1413-47
0407-1413-86
0407-1413-87
0407-1413-88

**Manufacturer(s)**

GE Healthcare, 251 Locke Drive, Marlborough, MA 01752, United States

**Problem**

1. Because of the current outbreak of COVID-19 in Shanghai, the iodine contrast material manufacturing facility was temporarily closed, creating a halt on the production of Omnipaque products. The facility has now reopened at reduced capacity with production output continuing to increase.
2. This situation is creating a very low stock of Omnipaque products, and some distributors are reporting it on backorder.
3. Diagnostic imaging studies that require iohexol contrast are being delayed or cancelled, including emergency studies. Also, the shortage may cause diagnosis delays.

#### **ECRI Recommendations:**

1. Reschedule non-urgent imaging studies that require iohexol contrast until there is an adequate supply.
2. Reserve iohexol for critical patients who require contrast-enhanced CT or cardiac catheterization procedures.
3. If possible, use Iopamidol (Isovue) as an alternative contrast agent.
4. If possible, use other imaging modalities, such as MRI or ultrasound.
5. If the use of a single vial iohexol for multiple patients is considered, follow the in-use time stated in the label only if the vial can be maintained in ISO Class 5 or cleaner air, per [USP 797](#).
6. During times of critical need, follow the [May 12, 2022, CDC guidance](#) on how contents from unopened single-dose vials can be repackaged for multiple patients.
  1. Repackaging of the product should only be performed if done under ISO Class 5 conditions by qualified healthcare personnel in accordance with standards in the United States Pharmacopeia General Chapter <797> Pharmaceutical Compounding-Sterile Preparation.
2. Coordinate with GE Healthcare and wholesalers to ensure that the allocated quantity is accurate based on historical purchases.
3. Consult ECRI's complimentary [Functional Equivalents Report](#) that provides information about marketed contrast media and lists vendor product availability. The report can also be used to identify equivalent products to assist in navigating product shortages. [covid\\_ecri\\_vendor-check\\_contrast-media.xlsx \(live.com\)](#)

#### **Background:**

1. Because of a city-wide COVID 19 lockdown in Shanghai, a manufacturing facility of iohexol iodinated contrast media was temporary closed.
2. This contrast material is used in routine imaging exams and emergency cases, including diagnosis of strokes, aneurysms, and for cardiovascular procedures.
3. The manufacture's facility closing was temporary. At the time of this publication, the facility has reopened at reduced capacity with production output continuing to increase.
4. Although the information was sent by GE Healthcare, other manufacturers of iohexol contrast may also have shortages of their contrast media products.

## Manufacturer's Perspectives

1. GE Healthcare sent an update [letter](#) on May 18, 2022, stating:
2. GE Healthcare is balancing supply of available product globally and has in some markets introduced measures to reduce order quantities but with a higher frequency of delivery, as well as optimizing production to focus on three main product variations.
3. GE Healthcare states this is a fluid situation they are working through daily, and the firm is keeping affected customers informed to enable them to plan accordingly.
4. GE Healthcare local sales and customer services representatives are available to assist with any questions.
5. GE Healthcare has increased capacity of iohexol in its Cork, Ireland manufacturing facility.

## UMDNS Term(s)

Contrast Media, Radiographic, Iodinated [41076]

## Geographic Region(s)

U.S.

## Suggested Distribution

Diagnostic Imaging, Risk Management/Continuous Quality Improvement, Radiation Oncology/Medical Physics, Pharmacy, Materials Management

## Comment

- This alert is a living document and may be updated when ECRI receives additional information.

## Miscellaneous

### References:

United States:

- FDA Drug Shortages. GE Healthcare. Iodixanol (Visipaque) Injection [online]. 2022 May 9 [cited 2022 May 20]. Available from Internet: [Click here](#).
- FDA Drug Shortages. GE Healthcare. Iohexol (Omnipaque) Injection [online]. 2022 May 9 [cited 2022 May 20]. Available from Internet: [Click here](#).