



GE Healthcare
Life Sciences
Pharmaceutical Diagnostics

100 Results Way
Marlborough, MA 01752

Subject: Temporary changes to availability of [Indium DTPA \(Indium In-111 Pentetate Disodium\)](#)

Dear Valued Customer,

We are writing to inform you of a current shortage of Sodium Bicarbonate Injection USP, impacting our ability to manufacture [Indium DTPA](#) on its regular weekly schedule. Sodium Bicarbonate Injection, USP, a key ingredient used in the formulation of Indium DTPA, is currently on the FDA drug shortage list, and subsequently unavailable to us at this time.

In order to minimize the effect this shortage, we will be temporarily amending the manufacturing schedule of Indium DTPA until an adequate resolution is implemented. Beginning February 6, 2020 we will begin manufacturing Indium DTPA every other week, and Indium DTPA will only be available during the weeks we manufacture.

We are committed to maintaining high standards in the industry, from manufacturing to customer delivery. Our experienced team is working hard to implement a solution as quickly as possible and minimize the impact of this shortage.

We want to reassure you that GE Healthcare remains committed to providing you with the highest-quality products and service level possible. We remain steadfast in working to do everything possible to restore weekly availability of this product, while continuing to provide you with the same exceptional service and quality that you have come to expect.

If you have any questions or concerns, please do not hesitate to reach out to your local GE Sales Representative. GE Pharmacy customers may also call 1-800-242-8004 to be connected with your local GE Pharmacy Manager for further assistance.

Best Regards,

A handwritten signature in dark ink, appearing to read 'M. Wysocki'.

Michael Wysocki, General Manager, US Molecular Imaging
GE Healthcare

Please see Important Safety Information on the following page as well as the [Full Prescribing Information](#) or visit our website at gehealthcare.com.

PRODUCT INDICATION: DTPA In-111 (Pentetate Indium Disodium In-111) is indicated for use in radionuclide cisternography.

Important Safety Information About Indium DTPA In-111 (Pentetate Indium Disodium In-111)

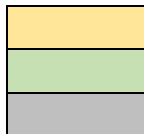
CONTRAINDICATIONS: None known. **WARNINGS AND PRECAUTIONS:** Since the kidneys excrete the drug, caution should be exercised in patients with severely impaired renal function. Discard vial after a single use. Do not use if contents are turbid. **Nursing Mothers:** It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, formula feedings should be substituted for breastfeedings. **Pediatric Use:** Safety and effectiveness in pediatric patients have not been established. **Geriatric Use:** Clinical experience has not identified differences in responses between the elderly and younger patients. The drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function. **ADVERSE REACTIONS:** Aseptic meningitis and pyrogenic reactions have been rarely observed following cisternography with Indium DTPA In-111. One death has been reported and appears to be drug related. Two cases of septic meningitis also have been reported. There also have been reports of skin reactions and vomiting following administration.

Prior to Indium DTPA In-111 administration, please read the full Prescribing Information.

To report SUSPECTED ADVERSE REACTIONS, contact GE Healthcare at 800 654 0118 (option 2, then option 1), or the FDA at 800 FDA 1088 or www.fda.gov/medwatch.

Temporary Indium DTPA Delivery Calendar

	Sun	Mon	Tue	Wed	Thu	Fri	Sat
February							1
	2	3	4	5	6	7	8
	9	10	11	12	13	14	15
	16	17	18	19	20	21	22
	23	24	25	26	27	28	29
March	1	2	3	4	5	6	7
	8	9	10	11	12	13	14
	15	16	17	18	19	20	21
	22	23	24	25	26	27	28
	29	30	31				
April				1	2	3	4
	5	6	7	8	9	10	11
	12	13	14	15	16	17	18
	19	20	21	22	23	24	25
	26	27	28	29	30		
May						1	2
	3	4	5	6	7	8	9
	10	11	12	13	14	15	16
	17	18	19	20	21	22	23
	24	25	26	27	28	29	30
	31						
June		1	2	3	4	5	6
	7	8	9	10	11	12	13
	Back to normal availability						
	14	15	16	17	18	19	20
	21	22	23	24	25	26	27
	28	29	30				



New Indium DTPA batch produced
Indium DTPA available for order/receipt
Indium DTPA unavailable for receipt