Good day!

The purpose of this announcement is to inform all the healthcare professional and the general public, that (FMEI) – Fernando Medical Enterprises, Inc. is voluntarily recalling the product as mentioned below:

DETAILS

Generic Name	Gadoteric Acid
Brand Name	Dotarem
Registration No.	DR-XY26429
Affected Batch/Lot No.	20GD080A
Manufacturing Date	October 2, 2020
Expiry Date	Sept. 30, 2023

History of trigger/hazard or reason for recall: Global voluntary recall due to the evidence of external leaks of the solutions (dry product on the external surface of the vials) due to a very small and hard to notice defect of the glass vial neck.

Indications of the product: Dotarem is a prescription gadolinium-based contrast agent indicated for intravenous use with magnetic resonance imaging (MRI) in brain (intracranial), spine and associated tissues in adult and pediatric patients (including term neonates) to detect and visualize areas with disruption of the blood brain barrier (BBB) and/or abnormal vascularity.

A "Dear Healthcare Professional Communication (DHPC) Letter" has been disseminated, wherein healthcare professionals are instructed to return the remaining stocks to the company.

Contact no./details: (FMEI) – Fernando Medical Enterprises, Inc.
02- 87379898

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph or through https://primaryreporting.who- umc.org/Reporting/Reporter?OrganizationID=PH.

Respectfully yours,

(FMEI) – Fernando Medical Enterprises, Inc.

Guerbet

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Dear Healthcare Professional Communication (DHPC) Letter # 2

Date: November 19th, 2021

Object: Quality defect impacting some batches of Dotarem 10 mL Vials

Recipients: Healthcare Professionals

Description of the problem and its management by Guerbet:

On November 10th, a subcontractor of Guerbet in charge of product labeling identified a few samples of Dotarem 10 mL Vials (batch # 21GD054) which presented with evidence of external leaks of the solution (dry product on the external surface of the vials). The root cause of the problem is a very small and hard to notice defect of the neck of the glass vials supplied by SGD Saint-Gobain. After investigation of the retained samples, a second batch of Dotarem 10 mL Vials (# 21GD006) was also identified with the same defect. Even if this defect is believed to affect only a very small number of vials in these batches, there is a potential sterility breach. Therefore, as a precautionary measure, Guerbet decided to trigger a batch recall in concertation with the health authorities of the concerned countries where those batches were distributed. On November 11th, a DHPC Letter # 1 was also elaborated and shared with health authorities before distribution.

In parallel, further investigations have been conducted at Guerbet manufacturing sites and with the supplier of the glass vials to see whether additional batches might also be affected by this problem. These investigations led to the identification of three other batches of Dotarem 10 mL Vials (# 20GD075A/B/C, # 20GD080A/B and # 20GD087A/B) which were manufactured with the defective batches of vials. No product leakage could be found on the retained samples of these batches, and no customer complaint has been received on these batches. However, as additional precautionary measure, Guerbet will trigger a recall for these three additional batches. Other vial sizes of Dotarem (15, 20, 60, 100 mL) are not affected by this problem.

As of today, Guerbet has not received any pharmacovigilance case associated with these five batches suggesting that patients have developed some signs of infection, a possible consequence of an injection of a non-sterile product.

Please, organize with your local Guerbet contact the return of all the vials which you have in stock for the batches # 20GD075A/B/C, # 20GD080A/B, # 20GD087A/B, # 21GD006A/B/C and # 21GD054A/B/C.

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Responsible Pharmacist