

Product Recall

October 18, 2019

Dear Healthcare Provider:

Problem Description Baxter Healthcare Corporation previously issued a voluntary product recall for certain lot numbers of the EXACTAMIX Empty EVA Bags (reference # FA-2018-045) due to the potential ability to leak once used for compounding. Baxter is expanding this recall to include the lot numbers listed in the enclosed Attachment A.

The EXACTAMIX Empty EVA bags are used as the destination container in compounding of large-volume sterile solutions for further administration to a single patient. The empty bags are used at pharmacies and compounding centers by pharmacists and pharmacy technicians to compound multi-ingredient solutions, as prescribed by a physician. The affected lots were distributed between June 2018 and July 2019 in the Singapore.

Affected Product

Product Code	Product Description	Lot Numbers
H938738	EXACTAMIX EVA Bag - 500mL	Refer to Attachment A
H938739	EXACTAMIX EVA Bag - 1000mL	Refer to Attachment A
H938741	EXACTAMIX EVA Bag - 3000mL	Refer to Attachment A

Do note: There are other identifiers and/or lots affected globally but not supply in Singapore. Kindly verify with Baxter if in doubt.

Hazard Involved

An undetected leak in the compounded IV solution bag may allow for microbial contamination of the solution which may lead to a bloodstream infection, or an air embolism caused by air entering the fluid path. There have been no reports of serious injuries associated with this issue globally.

There have no adverse event/ serious injuries/ death cases report in Singapore.

Actions to be taken by Customers

1. Locate and remove all affected product lots from your facility. The product code and lot number can be found on the individual product and shipping carton.
2. Complete the enclosed Baxter Customer Reply Form and return it to Baxter by scanning and e-mailing to Baxter Sales Representative. Returning the Baxter Customer Reply Form promptly will prevent you from receiving repeat notices.
3. The affected product should be returned by contacting Baxter Sales Representative.
4. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.



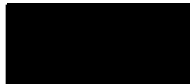
The Health Sciences Authority has been notified of this action. If you have questions regarding this communication or if you have any other questions, please call your Baxter Sales Representative or e-mail to Sabrina Mok [REDACTED]

Please kindly report any quality problems or any adverse events associated with the product to the following personnel:

- Please report Product Complaints to singapore_productcomplaint@baxter.com
- Please report Adverse Events to singapore_patientsafety@baxter.com

We apologize for any inconvenience this may cause you and your staff.

Sincerely,



Corynn Tan
Senior QA Manager
Baxter Healthcare (Asia) Pte Ltd

cc: Director of Pharmacy, Chairman Medical Board and relevant Head of Departments

Enclosure: Baxter Customer Reply Form
Attachment A: Affected Lot Numbers

Attachment A: Affected Lot Numbers

Product Code	Product Description	Lot Number
H938738	EXACTAMIX EVA Bag - 500mL	60108276
		60116878
		60119804
		60120941
		60124653
		60134196
		60135995
		60137713
		60146637
		60149811
		60155175
		60157743
		60161568
H938739	EXACTAMIX EVA Bag - 1000mL	60120571
		60125601
		60132904
		60140847
		60148487
		60155998
		60158795
		60160925
H938741	EXACTAMIX EVA Bag - 3000mL	60105202
		60105405
		60105406
		60108444
		60130038
		60132224
		60137157