REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٨١/٢٥
رقم الصادر : ١٢/١/٢٥٢٣٢
بيروت، في : ٣١ كانون الثاني ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس
INFUSOR and INTERMATE Portable Elastomeric Infusion Systems

الجهاز المعني بالمتابعة:

- INFUSOR and INTERMATE Portable Elastomeric Infusion Systems
- Trade Mark: Baxter Healthcare
- Local Representative:

نرجو الاطلاع على التوصية الصادرة عن وكالة
Medicine and Health Care Products Regulatory Agency (UK) MHRA
والتوصية الصادرة عن الشركة المصنعة والتي تشير الى خلل في عمل الصنف الوارد أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار

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PRODUCT SAFETY ALERT

September 2013

Subject: Field Safety Notice – Infusor / Folfusor / Intermate portable elastomeric infusion systems

Product codes: Please refer to the Attachment 1

Lot numbers: all

Dear Chief Pharmacist

Issue Description

Baxter Healthcare Ltd is providing you with important safety information regarding the INFUSOR, FOLFUSOR, and INTERMATE portable elastomeric infusion systems. Please see Attachment 1 for listing of all applicable product codes.

Baxter has received complaints for infusion flow rates greater than intended for the above referenced portable elastomeric infusion systems. In many cases, the complaint details an overinfusion of medication that are the result of uses inconsistent with the Instructions for Use.

Hazard Involved

Delivery of medication at an infusion rate faster than intended may lead to toxicity and changes to efficacy that require medical intervention.

Action to be taken by healthcare providers

Baxter is requesting that healthcare providers continue to follow the device Instructions for Use which explains the following factors that may impact resulting flow rate:

1. The choice of medication: Refer to the drug manufacturer's package insert for drug reconstitution/dilution and storage procedures.
2. Instructions for calculating the correct fill volumes including the potential for increase in flow rate which may result from a fill volume below the stated nominal fill volume.
3. Temperature change on the device.
4. Choice of the diluents (5% Dextrose vs. 0.9% Sodium Chloride) as a ~10%

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increase in nominal flow rate may result when 0.9% Sodium Chloride is used.

5. The position of the Elastomeric Reservoir in relation to the Distal End Luer Lock. Flow rate will decrease ~0.5% for every inch the Elastomeric Reservoir is positioned below the distal end luer lock and increase ~0.5% for every inch the elastomeric reservoir is positioned above the distal end luer lock.

6. Length, diameter, and location of catheter

Action to be taken in response to this notification

Baxter is requesting that you take the following actions in response to this notification:

1. Acknowledge your receipt of this Safety Alert notification by completing the attached Customer Reply Form (Attachment 2) and return it to Baxter by using the contact details provided on the faxback form. Returning the Customer Reply Form promptly will prevent you from receiving repeat notifications.

2. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them to ensure that they are aware of this notice.

3. If you are a dealer, wholesaler, or distributor/reseller that distributed any product to other facilities, please notify your customers of this action.

Should you have any clinical questions related to this please contact Surecall Baxter Medical Information on 01635 206345 or email surecall@baxter.com.

Any adverse reactions or quality problems experienced with the use of these products may be reported using one of the following options:

Reporting product quality complaints:
- Calling 01604 704 603
- Faxing to: 01604 704688
- Emailing to: uk_shs_qad@baxter.com

Reporting adverse events with drugs:
- Calling 01635 206 360,
- Faxing to: 01635 206 281,
- Emailing to: vigilanceuk@baxter.com

The MHRA has been notified of this action.

Sincerely,

J. Lorimer

Joanna Lorimer
Product Manager
Medical Products
Baxter Healthcare Ltd, Wallingford Road
Compton, Newbury, Berkshire RG20 7QW

Attachment 1: INFUSOR / FOLFUSOR / INTERMATE Product Code Listing
Attachment 2: Customer Reply Form

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Attachment 1

Safety Alert – INFUSOR / FOLFUSOR / INTERMATE Product Code Listing

PRODUCT CODE	DESCRIPTION
INFUSOR – Portable Elastomeric Infusion System	
2C1071KJP	Singleday INFUSOR
2C1073KJP	Half Day INFUSOR
2C1075KJP	Two Day INFUSOR
2C1080KJP	Multiday INFUSOR
2C1082KJP	Seven Day INFUSOR
S2C1083KJP	Desferrioxamine INFUSOR
INFUSOR LV - Portable Elastomeric Infusion System	
2C1087KP	INFUSOR LV 1.5
2C1008KP	INFUSOR LV 2
2C1009KP	INFUSOR LV 5
2C1156KP	INFUSOR LV 7
2C1063KP	INFUSOR LV 10
INFUSOR SV - Portable Elastomeric Infusion System	
2C1700KP	INFUSOR SV 0.5
2C1701KP	INFUSOR SV 1
2C1702KP	INFUSOR SV 2
INFUSOR XLV - Portable Elastomeric Infusion System	
2C1168K	INFUSOR XLV 8
FOLFusor - Portable Elstomeric Infusion System	

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2C4701K	FOLFusor SV 1
2C4711K	FOLFusor SV 2.5
2C4009K	FOLFusor LV 5
2C4063K	FOLFusor LV 10
Basal/Bolus INFUSOR - Portable Elastomeric Infusion System	
2C1976KJ	Basal/Bolus INFUSOR 2 ml/h x 2 ml/h System
MULTIRATE INFUSOR - Portable Elastomeric Infusion System	
2C1154KP	MULTIRATE INFUSOR SV 1.0-2.0-3.0
2C1155KP	MULTIRATE INFUSOR LV 2.0-3.0-5.0
2C9960KP	MULTIRATE INFUSOR LV 5-7-12
2C9961KP	MULTIRATE INFUSOR LV 2.0-4.0-6.0
Regional Analgesia INFUSOR System with Patient Control Module	
2C1811K	Regional Analgesia INFUSOR System with Patient Control Module 5.0-7.0-12.0
INTERMATE - Portable Elastomeric Infusion System	
2C1710K	INTERMATE SV 50 -Single-pack
2C1730K	INTERMATE SV 50 -Multi-pack
2C1712K	INTERMATE SV 100 - Single-pack
2C1732K	INTERMATE SV 100 - Multi-pack
2C1714K	INTERMATE SV 200 - Single-pack
2C1734K	INTERMATE SV 200 - Multi-pack
2C1720K	INTERMATE LV 50 - Single-pack
2C1742K	INTERMATE LV 100 - Multi-pack
2C1724K	INTERMATE LV 250
2C1744K	INTERMATE LV 250
2C1754K	INTERMATE XLV 250
2C1064K	INTERMATE XLV 250