

Date 07th July 2015

Dear Customer

Affected Product	Product Code	Description	Lot #	Expiration Date
	UKF7114	Sterile Water for Irrigation, 1000mL	14H12BA1A	31 July 2017
	UKF7124	0.9% Sodium Chloride for Irrigation	14H11BB1A	31 July 2017

Problem Description

Baxter Healthcare is issuing a voluntary recall of the above mentioned products following a customer complaint that was received on 25th June 2015 referring to “salty” taste of a unit of Sterile Water for irrigation (UKF7114, 14H12BA1A).

The analysis of the returned samples were conducted and confirmed to contain 0.9% Sodium Chloride solution labelled as Sterile Water for Irrigation.

Initial investigation has revealed that a potential root cause for this issue could be a mix-up during the labelling process.

Sterile water for irrigation is hypotonic. If it is mistaken for 0.9% Sodium Chloride and used for continuous irrigation or allowed to dwell inside body cavities, absorption into the blood stream may occur resulting in hemolysis, hyponatremia or fluid overload.

0.9% Sodium Chloride for irrigation is isotonic. It should be used with caution in patients with congestive heart failure, severe renal insufficiency or clinical states in where there exists sodium retention.

Action to be taken by the user

Baxter is kindly asking that you take the following actions:

1. Locate and remove all affected product from your facility. The product code and lot number can be found on the individual product and the shipping carton.
2. Complete the enclosed customer reply form, and return it to Baxter by either faxing it to 01 206 5577 or scanning and e-mailing it to QA_Dublin@baxter.com even if you don't have any inventory. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

3. Baxter will contact you to organise return and replacement of the recalled products.
4. If you are a dealer, wholesaler, or distributor/reseller that distributed affected product to other facilities, please conduct a recall with your end-user customers in accordance with your customary procedures.

**Further
information
and support**

For general questions regarding this communication, contact your local Baxter Representative.

Please note that the Health Products Regulatory Authority (HPRA) has been notified.

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

Yours Sincerely,



Ian Gavigan
Head of CQA UK/Ireland
Baxter Healthcare Ltd.
Deansgrange Business Park
Blackrock
Co. Dublin
Ph: 01 2065500

Attachment 1: Customer Reply Form

CUSTOMER REPLY FORM related to Product Recall letter dated 07th July 2015

PRODUCT NAME: Sterile Water for Irrigation, 1000mL
Product code: UKF7114 Batch Number: 14H12BA1A

PRODUCT NAME: 0.9% Sodium Chloride for Irrigation
Product code: UKF7124 Batch Number: 14H11BB1A

Please complete and return one copy of this form per facility either by fax (Fax: 01 206 5577) or by e-mail (QA_Dublin@baxter.com) as confirmation that you have received this notification. A fax cover sheet is not required.

Facility Name and Address:	
Reply Confirmation Completed By (<i>Please Print</i>):	
Title (<i>Please print</i>):	
Email and/or Telephone Number (including Area Code):	

Please check boxes as appropriate:

- We do not have any of the affected lots in our inventory.
- We do have the affected lots in our inventory and products have been quarantined.

Please list the quantity of the specific lot(s) to be returned below*:

Product Code	Lot number	Quantity in units to be returned

*You may attach an additional sheet if required.

Please quarantine all affected product and prevent from use until it is collected by Baxter

Your signature below indicates that you have received the attached letter; performed the actions as outlined in the letter as needed; and disseminated this information to staff and other services or facilities as applicable.

Signature/Date: REQUIRED FIELD	
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