

REPUBLIQUE LIBANAISE

MINISTÈRE DE LA SANTÉ PUBLIQUE

LE DIRECTEUR GÉNÉRAL



الجمهورية اللبنانية

وزارة الصحة العامة

المدير العام

رقم المحفوظات: ٢٩٢٥

رقم الصادر: ١٢/١/١٥٢٣٥

بيروت، في: ٢٠ أيار ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس.

الجهاز المعنى بالمتابعة:

- Bone Substitute, ACTIFUSE ABX, Actifuse MIS
- Trade Mark: Baxter Healthcare
- Local Representative:

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي تفيّد بوجود مضاعفات ناتجة عن استعمال

المادة المذكورة أعلاه ، نرجو منكم تعميم هذه النشرة على المستشفيات المعنية.

مرفق ربطا:

- التوصية الصادرة عن الشركة المصنعة.

يبلغ:

- دائرة البرامج والمشاريع
- الموقع الإلكتروني لوزارة الصحة
- المحفوظات

مدير عام الصحة

د. وليد عمار



وثيقة مصدقة للأصغر  
بيروت في ٢٠ أيار ٢٠١٢  
دبس نسر امانة السم  
عناية خصص



**Baxter**  
(Customer letter)

**IMPORTANT  
PRODUCT  
INFORMATION**

05th September 2012

**Subject : Use of ACTIFUSE ABX and ACTIFUSE MIS Synthetic Bone Substitute in Pediatric Patients with Large Bone Cysts**

Products Concerned: Actifuse ABX and Actifuse MIS Synthetic Bone Substitute

Product Codes Concerned: 506005078048, 506005078048, 506005078049, 506005078057, 506005078059, 506005078069, 506005078071

Dear Theatre Manager / Surgeon,

Baxter is providing you with **important product information** regarding ACTIFUSE ABX and ACTIFUSE MIS Synthetic Bone Substitute.

This product communication is being provided as a result of isolated reports of postoperative fever and inflammatory reactions (in the absence of bacterial infection) with use of Actifuse ABX in paediatric patients undergoing surgical removal of large juvenile bone cysts. The reported side effects had no negative impact on therapeutic outcome or function of the ACTIFUSE ABX product.

While this patient group represents a small and highly select population of ACTIFUSE ABX patients, a causal relationship cannot be confirmed but can also not be fully excluded. A precautionary statement will be added to the ACTIFUSE ABX and ACTIFUSE MIS Instructions for Use as follows:

*"Actifuse should be used with caution in paediatric cases harboring large Juvenile Bone Cysts. Isolated cases of transient postoperative fever and inflammatory reaction, in the absence of infection have been reported from clinical experience with extremely large cysts. This side effect had no impact on the therapeutic outcome."*

**Please note that you are not being asked to return any product. You can continue to use ACTIFUSE ABX and ACTIFUSE MIS according to the Instructions for use and this important product information.**

If you provide this product to other services/facilities/departments, please forward this information as appropriate to ensure correct ACTIFUSE ABX and ACTIFUSE MIS utilization in your institution.

This important product information is being sent by mail with return receipt. The return receipt serves as confirmation of receipt for our documentation. The Medicines and Healthcare Regulatory Authority has been informed about this action.

If you have any questions please contact Baxter at Surecall Baxter Medical Information on 01635 206345 or [surecall@baxter.com](mailto:surecall@baxter.com).

Sincerely,

A handwritten signature in black ink that reads "Richard Coghill". The signature is written in a cursive style with a horizontal line under the name.

Richard Coghill  
Business Unit Manager BioSurgery, Baxter Healthcare